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(71) Applicant: VENTRICA, INC. [US/US]; 976 Hamilton Avenue, Menlo Park, CA 94025 (US).

(72) Inventor: FOLEY, Mark, J.; 1151 Hobart Street, Menlo Park, CA 94025 (US).

(74) Agents: HESLIN, James, M. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).

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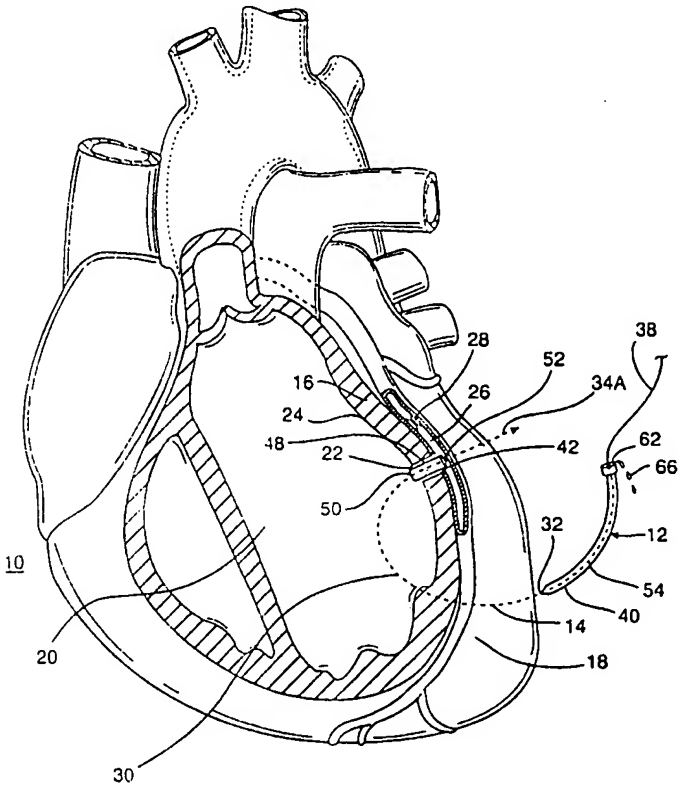
(54) Title: METHODS AND DEVICES PROVIDING TRANSMYOCARDIAL BLOOD FLOW TO THE ARTERIAL VASCULAR SYSTEM OF THE HEART

(57) Abstract

Methods and devices providing transmyocardial blood flow or coronary revascularization for the treatment of coronary atherosclerosis and resulting myocardial ischemia by increasing the flow of blood from one or more oxygenated blood sources within the patient to one or more sites selected in the arterial vascular system of the heart using a channel (42) for maintaining and regulating blood flow therebetween. A valved conduit (48) or a self-maintained channel (42) is created between the left ventricle (20) reservoir of oxygenated blood and the coronary artery (26) distal to an area of obstruction by surgical and percutaneous methods. Preferably, the conduit (48) or self-maintaining channel (42) integrally regulates the flow of blood between the oxygenated blood source and the site selected in the arterial vascular system of the heart wherein an increase in blood flow is desired.



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METHODS AND DEVICES PROVIDING TRANSMYOCARDIAL BLOOD FLOW TO THE ARTERIAL VASCULAR SYSTEM OF THE HEART

Field Of The Invention

This invention relates to methods and devices providing transmyocardial blood flow or coronary revascularization for the treatment of coronary atherosclerosis and resulting myocardial ischemia. The invention increases the flow of blood from one or more oxygenated blood sources within the patient to one or more sites selected in the arterial vascular system of the heart using a channel for maintaining and regulating blood flow therebetween. More particularly, a valve is inserted into a channel created and maintained between, or a valved conduit is inserted between, the left ventricle reservoir of oxygenated blood and the coronary artery distal to an area of obstruction.

Background Of The Invention

Heart disease is a major medical ailment wherein arteries become narrowed or blocked with a build-up of atherosclerotic plaque or clot which reduces flow to tissues downstream or "distal" to the blockage. When this flow reduction becomes significant, a patient's quality of life may be significantly reduced. In fact, heart disease patients often die when coronary arteries become significantly blocked.

However, technology has been developed to treat patients with coronary artery disease. Besides drug treatment, the two most common operative procedures used to treat symptomatic patients are: coronary artery bypass graft (CABG) surgery and percutaneous transluminal coronary angioplasty (PTCA).

Conventional CABG surgery affixes a bypass graft between a port or aperture in a coronary artery wall distal to the blockage and a pressurized arterial blood supply, such as the aorta, to provide a conduit for blood flow into the coronary artery to the ischemic areas of the heart. CABG surgery is generally initiated by directly exposing the heart to the surgeon by opening the patient's chest using known sternotomy and retraction

techniques that cut the sternum and spread the rib cage open. Once the heart is exposed, the patient is connected to a cardiopulmonary bypass ("CPB") machine so that the blood supply circumvents the heart. In this way, the heart is depressurized so that apertures can be cut into the walls of the vessels for surgical graft attachment. The right atrium (or vena cava) and the aorta each is intubated with cannulas which are connected to an artificial pump and oxygenator. Once these major vessels are cannulated, the aorta is then clamped proximally of the aortic bypass cannula, thereby isolating the aortic root and heart from the blood that is being circulated by the CPB. Cardioplegia is then delivered to stop the beating motion of the heart.

In one type of CABG method, the bypass grafting is achieved between the aorta and one of the three major coronary arteries or their sub-branches, the left anterior descending artery (LAD), the circumflex artery (CIRC), or the right coronary artery (RCA). In such a case, a saphenous vein is usually taken from the patient's leg and is transplanted as a "homograft" to connect these vessels in order to provide blood flow to the compromised area of the coronary circulation. Artificial grafts have also been disclosed as providing potential utility for this purpose. An alternative CABG method uses the internal mammary artery (IMA) alone or in conjunction with the saphenous vein graft. The IMA is severed at a chosen location and is then connected to an aperture in a coronary artery. The fluid connections between a graft and a vessel are commonly referred to as "anastomoses." Once the anastomosis of the bypass graft is complete, the heart is resuscitated and the patient is removed from CPB.

Although CABG surgery grafts have good long patency rates of about 60% to 90% over a ten year period, the isolation of the heart with the CPB and aortic cross-clamp carries a significant risk of mortality. It is believed that three critical determinants which affect outcomes of CABG surgery are: (1) time the patient spends on bypass, (2) time the patient spends with a clamped aorta, and (3) the quality of the anastomoses. It is generally believed that a CABG patient's operative and peri-operative morbidity are directly related to how long the patient must be on CPB. During prolonged periods on CPB, there is a greater chance for air and platelet embolization resulting from the artificial circuit. For example, such debris can embolize into the neurovasculature and potentially cause a stroke. In analyzing the timing of individual CABG steps against the backdrop of a patient's critical time on CPB, the time spent anastomosing the grafts to vessels emerges as a controlling factor. Closely related to the time spent on CPB is a

second CABG success factor related to the extent and time of aortic cross-clamping. It is believed that the inherent crushing force from a cross-clamp across the bridge of the muscular aortic arch may be associated with a high degree of tissue trauma and structural damage. Additionally, blood clots formed at or adjacent to the cross clamp, perhaps in conjunction with the tissue trauma of clamping, may also be a source of unwanted complications. In addition to the potential clinical complications associated with CABG surgery is also the cost of the time-consuming procedure.

In the PTCA procedures, a small incision is made in the patient's thigh to introduce a catheter into the femoral artery. The catheter is guided to the internal blockage site via x-ray visualization. The blockage is then treated remotely by use of hydraulic pressure in the case of balloon angioplasty wherein a balloon is inflated within the narrowed vessel to stretch or otherwise deform the blockage into a larger lumen. Or, in the case of atherectomy, other actuating means can be used to cause remote cutting or ablation of the blockage. In another approach, a stent is used to scaffold open the blocked area of the artery. Although these procedures are less traumatic than CABG surgery, the failure rate is often about 30-50% whereby the vessel narrows within a six month period and must be treated again.

Due to the limitations with these operative techniques, alternate methods have been proposed. For example, US Patent 5,655,548 by Nelson et al. discloses open surgical and transluminal methods for supplying long-term retrograde perfusion of the myocardium via a conduit disposed between the left ventricle and the coronary sinus. Blood ejected from the left ventricle enters the coronary sinus during cardiac systole. The outlet from the left ventricle to the coronary sinus may include a one-way valve to prevent backflow from the coronary sinus into the left ventricle during cardiac diastole. The long-term artero-venous fistula that is created, however, has the potential for edema or other physiologic effects.

Another alternate method is disclosed in international patent applications: WO 97/27897, WO 97/27893, WO 97/13463, WO 97/13471, and WO 97/27898; wherein a percutaneous, transluminal approach is described which requires an adjacent cardiac vein to perform the procedure. Unfortunately, most coronary arteries do not have adjacent cardiac veins and, thus, the disclosed approach may be limited in its ability to provide full revascularization.

Another method is disclosed by Wilk in US Patents 5,429,144, 5,287,861, 5,662,124 and 5,409,919, wherein an expandable stent is disposed in the myocardium by a percutaneous approach through the coronary artery requiring no incision through the chest. The method requires that the expandable stent be initially collapsed, ejected from a catheter into the myocardium, and subsequently expanded with an inflatable balloon in the myocardium. The expandable stent extends only partially through the myocardium, from the left ventricle of the heart or from a coronary artery, upstream of a vascular obstruction. Alternatively, the expandable stent can extend through the myocardium between the left ventricle and the coronary artery, but is completely within the myocardium and not extending into either the left ventricle or coronary artery. The purpose of the expandable stent is to establish blood flow to the myocardium, and in some instances, to the coronary artery. One design of the expandable stent is to collapse and close during systole. In an alternate design, the expandable stent can resist the contractive pressure of the heart to remain open during systole to permit the flow of blood through the stent into the myocardium and coronary artery. During diastole, the blood pumped into the coronary artery through the expandable stent can be blocked from returning to the left ventricle by an integrated, one-way valve.

Among the drawbacks in using the Wilk method is that the stent must be expandable and any valve therein must be integral with the stent. The expandable stent is also sized to be only within, and not beyond, the myocardium. The expandable stent fails to accommodate changes in the thickness of the myocardium wall during the rhythmic contraction of the heart which, according to Feigenbaum's textbook of Echocardiography, changes from an average thickness of about 8mm in diastole to about 13mm in systole. The transluminal approach disclosed by Wilk can also have difficulty in delivering the expandable stent across coronary arteries which are substantially occluded. Approximately 60% of CABG surgery procedures are performed on totally occluded vessels where percutaneous access would not be feasible.

Ever since the discovery by Wearn, as reported in the "The Nature of the Vascular Communications Between the Coronary Arteries and the Chambers of the Heart", American Heart Journal, Volume 9, Number 2, 1933, that the myocardium is composed of a vast, sinusoidal network, people have attempted to revascularize the heart muscle directly. In 1957, Massimo and Boffi reported experiments in the Journal of Thoracic Surgery, Volume 34, Number 2, with T-shaped tubes that were implanted

directly into the myocardium in order to maintain a fluid channel between the left ventricle and myocardium. Another approach pioneered by Vineberg, "Coronary Vascular Anastomoses by Internal Mammary Artery Implantation", Canad. M.A.J., Volume 78, June 1, 1958, focused on the implantation of the IMA directly into the myocardium. In 1965, Sen et al., "Transmyocardial Acupuncture", Journal of Thoracic and Cardiovascular Surgery, Volume 50, Number 2, 1995, performed transmyocardial acupuncture which became the precursor to laser-assisted transmyocardial revascularization (TMR) in 1986, wherein multiple laser pin holes are made in the compromised myocardial area and into the left ventricle. However, these holes do not maintain a channel between the left ventricle and the native coronary circulation. Also, these holes are not maintained in an open state once they are formed. It is surmised that the benefit of the TMR approach is that it stimulates angiogenesis (new vessel growth) rather than maintaining new channels of perfusion.

There have been several studies that clearly teach away from the transmyocardial arterial revascularization described in the present invention. In a study similar to Sen et al., the authors Pifarré et al., reported in "Myocardial Revascularization by Transmyocardial Acupuncture: A Physiologic Impossibility", Journal of Thoracic and Cardiovascular Surgery, Volume 58, Number 3, 1969, attempts to revascularize the myocardium by coring out sections of the muscle to create a left ventricle to myocardial connection. They concluded that "...no blood flow is possible from the ventricle to the myocardium."

Another article "The Possibility of Myocardial Revascularization by Creation of a Left Ventriculocoronary Artery Fistula" by Ian Munro and Peter Allen, Journal of Thoracic and Cardiovascular Surgery, Volume 58, Number 1, 1969, discloses an attempt to revascularize an ischemic myocardium by constructing a fistula between the cavity of the left ventricle and the coronary circulation. Two conclusions drawn from the experimental results again teach away from the present invention. "First, any attempts to revascularize the wall of the left ventricle direct from the cavity of the ventricle are likely to be functional failures, even if technically successful...In addition, there was a failure of myocardial contractility and a rise in left ventricular and diastolic pressure. It was concluded that operations designed to revascularize the myocardium direct from the cavity of the left ventricle make the myocardium ischemic and are unlikely to succeed."

While other attempts have been made to reduce the complications associated with "CABG" surgery through less-invasive, standard surgical approaches, they have been limited in their ability to fully revascularize the heart and provide a comparable degree of long-term success. The prior art fails to disclose or fulfill the need for transmyocardial blood flow or coronary revascularization using a beating heart approach with either surgical or percutaneous techniques to create and maintain one or more regulated channels between the left ventricle and the arterial vascular system of the heart. The present invention also potentially eliminates the need for harvesting autologous bypass graft material that can be in short supply, contributes to the morbidity of the CABG procedure, and can compromise the vascular system.

Summary Of The Invention

The present invention provides a method for increasing the flow of blood to a selected site in a patient's arterial vascular system of the heart. The method includes the steps of: creating a channel for blood flow from an oxygenated blood source to the selected site in the arterial vascular system of the heart; maintaining the channel in an open position for blood flow through diastolic and systolic cycles of the heart; and regulating the blood flow in the channel to minimize blood flow from the coronary vascular system to the blood source during diastolic cycle of the heart.

The present invention also provides a method for performing a transmyocardial coronary revascularization procedure for the treatment of coronary atherosclerosis caused by an obstruction in the arterial vascular system. The method includes the steps of: creating a channel for blood flow from an oxygenated blood source to the arterial vascular system distal to the area of obstruction; maintaining the channel in an open position for blood flow through the diastolic and systolic phases of the heart cycle; and regulating the blood flow in the channel to minimize blood flow from the arterial vascular system to the blood source during the diastolic phase of the heart cycle.

A method for treating an obstruction in a patient's cardiovascular system using a non-expandable conduit made of biocompatible material is also provided by the present invention. The method includes the steps of: inserting the conduit completely through the myocardium of the patient's heart with one end of the conduit extending into the left ventricle and the other end of the conduit extending into the arterial vascular system distal to the area of obstruction; maintaining the conduit in an open position for blood flow

through the diastolic and systolic phases of the heart cycle; and regulating the blood flow in the channel to minimize blood flow from the arterial vascular system to the left ventricle during the diastolic cycle of the heart.

Another method provided by the present invention increases the flow of blood to a selected site in a patient's arterial vascular system. The method includes the steps of: inserting one end of a conduit into the left ventricle; inserting the second end of the conduit into the arterial vascular system at the selected site; maintaining the conduit in an open position for blood flow through the diastolic and systolic cycles of the heart; and regulating the blood flow in the conduit to minimize blood flow from the arterial vascular system to the left ventricle during the systolic phase of the heart cycle.

The present invention also includes conduits for maintaining a channel between an oxygenated blood source and a site in the arterial vascular system of the heart selected for delivering an increase of blood flow thereto. The conduit includes a tubular body having an inlet end and outlet end between the blood source and selected site, respectively. Preferably, the conduit includes means for regulating the flow of blood between the blood source and selected site. The conduit can include means for retaining the conduit in the myocardium with the inlet end extending into the left ventricle. Optionally, the conduit includes means for adjusting the conduit to the change of thickness of the myocardium during the heart cycle.

The present invention also provides a self-maintained channel created between an oxygenated blood source and a site in the arterial vascular system of the heart selected for delivering an increase of blood flow thereto. The self-maintained channel maintains an open position during at least a portion of the heart cycle. The self-maintained channel includes an inlet end and outlet end between the blood source and selected site, respectively. Preferably, the self-maintained channel includes an integral means for regulating the flow of blood between the blood source and selected site. Optionally, the self-maintained channel includes a natural or synthetic valve positioned therein as the regulating means.

Brief Description of the Drawing

Fig. 1 is a schematic cross-sectional view of a human heart showing a conduit inserted by a surgical method into a channel created from the left ventricle to a coronary artery in accordance with the present invention;

Fig. 2 is a side view of another embodiment of the needle assembly illustrated in Fig. 1 for creating and dilating an access port in the myocardium or other tissue layer in accordance with the present invention;

Fig. 3 is a side view of a delivery assembly for inserting a conduit into the myocardium or other tissue layer in accordance with the present invention;

Fig. 4 is a schematic cross-sectional view of a human heart showing a conduit inserted by a surgical method into a channel created from a coronary artery to the left ventricle in accordance with the present invention;

Fig. 5 is an integrated assembly to perforate, dilate, and insert a conduit into a channel in the myocardium or other tissue layer in accordance with the present invention;

Fig. 6 is a schematic cross-sectional view of a human heart showing a conduit inserted by a surgical method into a channel created from a coronary artery and the left ventricle in accordance with the present invention;

Fig. 7 is another embodiment of an integrated assembly to perforate, dilate, and insert a conduit into a channel in the myocardium or other tissue layer in accordance with the present invention;

Fig. 8 is a schematic cross-sectional view of a human heart showing a conduit inserted by a surgical method into a channel created from a coronary artery, both distal and proximal to a blockage , and to the left ventricle in accordance with the present invention;

Fig. 9 is a schematic cross-sectional view of a human heart showing a conduit inserted by a surgical method into a channel created along an extended portion of the myocardium from a coronary artery, both distal and proximal to a blockage , and to the left ventricle in accordance with the present invention;

Fig. 10 is a schematic cross-sectional view of a portion of the human heart showing a conduit inserted by a surgical method into a channel created from a coronary artery to a coronary vein and into the left ventricle in accordance with the present invention;

Fig. 11 is a schematic cross-sectional view of a portion of the human heart showing a conduit inserted by a surgical method into a channel created from a coronary vein into both a coronary artery and the left ventricle in accordance with the present invention;

Fig. 12 is a schematic cross-sectional view of a portion of the human heart showing a conduit inserted by a surgical method into a channel created from a coronary artery, both distal and proximal to a blockage , through a coronary vein and into the left ventricle in accordance with the present invention;

Fig. 13 is partial cross-sectional view of a conduit positioned within the myocardium in accordance with the present invention;

Fig. 14 is a schematic cross-sectional view of a human heart showing a conduit inserted by a percutaneous method into a channel created from the left ventricle to a coronary artery in accordance with the present invention;

Fig. 14A is an enlarged view of the area encircled in Fig. 14;

Fig. 15 is a schematic cross-sectional view of a human heart showing a conduit inserted by a percutaneous method into a channel created from a coronary artery to the left ventricle in accordance with the present invention;

Fig. 15A is an enlarged view of the area encircled in Fig. 15;

Fig. 16 is an integrated assembly to percutaneously perforate, dilate, and insert a conduit into a channel in the myocardium or other tissue layer in accordance with the present invention;

Fig. 17 is a schematic cross-sectional view of a portion of the human heart showing a conduit inserted by a percutaneous method into a channel created from a coronary artery to a coronary vein and into the left ventricle in accordance with the present invention;

Fig. 18 is a schematic cross-sectional view of a portion of the human heart showing a conduit inserted by a percutaneous method into a channel created from a coronary artery into a coronary vein distal to the channel into the left ventricle in accordance with the present invention;

Fig. 19 is a schematic cross-sectional view of a portion of the human heart showing a conduit inserted by a percutaneous method into a channel created from a coronary artery, both distal and proximal to a blockage , through a coronary vein and into the left ventricle in accordance with the present invention;

Fig. 20 is a cross sectional view of an embodiment of the valved conduit having projections as retaining means in accordance with the present invention;

Fig. 21 is a cross sectional view of another embodiment of the valved conduit having projections as retaining means in accordance with the present invention;

Fig. 23 is a cross sectional view of an embodiment of the valved conduit having a thread as retaining means in accordance with the present invention;

Fig. 25 is a cross sectional view of an embodiment of the valved conduit having a flared end as retaining means in accordance with the present invention;

Fig. 24 is a cross sectional view of an embodiment of the valved conduit having a coating as retaining means in accordance with the present invention;

Fig. 25 is a cross sectional view of an embodiment of the valved conduit having slots as retaining means in accordance with the present invention;

Fig. 26A and 26B are cross sectional views of the myocardium changing thickness along a conduit during systole and diastole, respectively, in accordance with the present invention;

Fig. 27 is a cross sectional view of an embodiment of the valved conduit having telescoping sections as adjusting means in accordance with the present invention;

Fig. 28 is a cross sectional view of an embodiment of the valved conduit having telescoping sections as adjusting means in accordance with the present invention;

Fig. 29 is a cross sectional view of an embodiment of the valved conduit having an accordion section as adjusting means in accordance with the present invention;

Fig. 30 is a cross sectional view of an embodiment of the valved conduit having a lateral accordion section as adjusting means in accordance with the present invention;

Fig. 31 is a cross sectional view of an embodiment of the valved conduit having a coil as adjusting means in accordance with the present invention;

Fig. 32 is a side view of an embodiment of the conduit having a branch configuration in accordance with the present invention;

Fig. 33 is a side view of an embodiment of the conduit having a hook configuration in accordance with the present invention;

Fig. 34 is a side view of an embodiment of the conduit having a hybrid synthetic/natural configuration in accordance with the present invention;

Fig. 35 is a cross sectional view of a vein used as a valve in accordance with the present invention;

Fig. 36 is a cross sectional view of another embodiment of a vein used as a valve in accordance with the present invention;

Fig. 37 is a cross sectional view of a valve in accordance with the present invention;

Fig. 38A and Fig. 38B are side views of a conduit regulating blood flow during two phases of the heart cycle in accordance with the present invention;

Fig. 39 is a cross sectional view of a valve in a self-maintained channel in the myocardium in accordance with the present invention;

Fig. 40 is an isolated front view of the valve in Fig. 39;

Fig. 41 is a cross sectional view of a self-maintained channel in the myocardium in accordance with the present invention; and

Fig. 42 is a cross sectional view of a self-maintained channel in the myocardium in accordance with the present invention.

Detailed Description Of The Invention

The present invention generally describes a transmyocardial approach wherein one or more new channels, which are preferably about the size of a coronary artery, are formed between the left ventricle or other oxygenated blood source and one or more sites in the arterial vascular system of the heart selected for increasing the flow of blood thereto. Preferably, the selected site is in a position distal to one or more obstructed areas within the coronary circulation. The channel is created by penetrating completely through the tissue defining the blood source, such as the myocardium which defines the left ventricle, or the vascular tissue, which defines a coronary artery. The channel is maintained in an open state, by mechanical means or through tissue removal, in order for blood to flow through during the cycle of the heart. The channel is regulated or valved controlling both the direction and/or the quantity of blood flow through the channel between the left ventricle and the selected site in the arterial vascular system of the heart.

The present invention includes several methods for creating and maintaining a channel in the myocardium for the purposes of connecting an oxygenated blood source to the arterial vascular system of the heart, compromised by a coronary blockage. The inventive methods include both surgical and percutaneous approaches. Generally, the surgical approaches include direct access to the exterior of the patient's heart via a chest or thoracic approach. The percutaneous approaches include a minimally invasive technique using catheters or other devices which are inserted into the patients' vessels or heart at a remote access site and guided to the internal blockage site via visualization by instrumentation. The revascularization is then accomplished remotely.

As defined herein, the term diastole refers to the normal rhythmical relaxation of the heart chamber, especially the ventricles, during which they fill with blood. The term systole refers to the rhythmic contraction of the heart, especially the ventricles, during which blood is driven through the aorta and pulmonary artery after each diastolic period. The term distal is generally defined as in the direction of the patient, or away from a user of a device, or in a downstream direction relative to a forward flow of blood. In the context of a medical device intervention with or through a vascular tissue layer, distal herein refers to the interior or the lumen side of the vascular tissue layer or wall. Conversely, proximal generally means away from the patient, or toward the user, or in an upstream direction relative to a forward flow of blood. In the context of a medical device intervention with or through a vascular tissue layer, proximal herein refers to the exterior or outer side of the vascular tissue layer or wall. The term arterial vascular system of the heart includes, but is not limited to, the myocardium and coronary arteries.

Although the present invention is specifically described below with regard to the coronary artery, it should be understood that the present invention is not so limited and that the description is applicable to any part of the arterial vascular system of the heart. For example and not limitation, the description is applicable to the left anterior descending artery, the circumflex artery, the right coronary artery, and their tributaries. The description is also specific with regard to the left ventricle, but is applicable to other oxygenated blood sources of the arterial vascular system such as the left anterior descending artery, the circumflex artery, the right coronary artery, and their tributaries proximal to any obstruction or blockage.

A preferred method of the present invention is a surgical approach which directly accesses and exposes the outside of the patient's heart and coronary vascular system 10 through the chest area using a needle assembly 12 as illustrated in Figs. 1 and 2. Similar components between the figures herein are denoted by the same reference numerals. An initial access port 14 in the myocardium is made by advancing the needle assembly 12 through the myocardium 16 from the exterior side 18 of the myocardium 16 and into the left ventricle 20. Then a second access port 22 in the myocardium is made from the interior side 24 of the myocardium within the left ventricle 20 and underneath the coronary artery 26. The needle assembly 12 is advanced through the myocardium 16 from the left ventricle 20 and into the coronary artery 26 at a point distal to the lesion or blockage 28.

After the needle assembly 12 has created the second access port 22, a guide wire 30 or other directional means is extended from the distal end 32 of the needle assembly into the coronary artery 26. A sufficient length of the guide wire 30 is advanced into the coronary artery 26 to prevent its premature withdrawal. Optionally, the distal end 34 of the guide wire can contain a balloon 36 or other temporary anchoring means to prevent premature withdrawal of the guide wire 30 from the coronary artery. The proximal end 38 of the guide wire extends through the left ventricle 20 to the exterior 18 of the myocardium where it is available for manipulation by the surgeon. With the guide wire 30 extending from the exterior 18 of the myocardium, through the left ventricle 20 and into the coronary artery 26, the needle component 40 of the assembly is withdrawn from both the initial and second access ports.

The method uses the connection made by the second access port 22 between the left ventricle 20 and the coronary artery 26 to create and maintain a channel 42 therebetween. The initial access port 14 is dilated to allow the advancement of a delivery device 44 as illustrated in Fig. 3 having a sheath 46 covering a valved conduit 48. The sheath 46 is configured to assist the passage of the valved conduit 48 through the initial access port 14 without snagging the valved conduit 48 or damaging the myocardium 16. The delivery device 44 is advanced over the guide wire 30, through the initial access port 14, and into the left ventricle 20. The guide wire 30 directs the delivery device 44 to the second access port 22. The valved conduit 48 is then removed from the sheath 46 with a pusher rod 74 and the delivery device 44 inserts the valved conduit 48 into the second access port 22 so that the valved conduit 48 extends through the myocardium 16 from the left ventricle 20 to the coronary artery 26. The conduit 48 keeps the second access port 22 dilated and maintains the channel 42 between the left ventricle 20 and the coronary artery 26. The end 50 of the conduit preferably extends into the left ventricle 20 during the rhythmic contractions of the heart. It is preferred that the valved conduit end 50 extends into the left ventricle 20 at least during diastole when the myocardium is at the minimal thickness of its cycle. The other end 52 of the conduit can be approximately flush with the exterior 18 of the myocardium or extends slightly into the coronary artery 26 during at least during diastole when the myocardium is at the minimal thickness of its cycle.

The remainder of the delivery device 44 is then withdrawn from the left ventricle 20 through the initial access port 14. Either simultaneous with or subsequent to the

Another embodiment of the present invention combines portions of different percutaneous approaches. As described in Fig. 15, a guide wire 238 is inserted into the coronary artery 26 from a remote access site such as along the femoral artery. The guide wire 238 is used to cross the blockage 28 and is advanced into the left ventricle 20. Using the path described in Fig. 14, a guide wire is advanced from the same access site into the left ventricle and is used to snare the guide wire 238 advanced from the coronary artery and retrieve the guide wire 238 back to the remote access site. As a result, the guide wire 238 completes a circuit from the remote access site through the coronary artery, across the myocardium, to the left ventricle and back to the remote access site. One or more devices can then be advanced through the left ventricle to the interior side of the myocardium without crossing the blockage in the coronary artery.

Another inventive method using the percutaneous approach which advances a catheter 260 into the coronary artery 26 from a remote access site such as along the femoral artery is illustrated in Fig. 17. Once the position of the catheter 260 is determined within the coronary artery 26, a penetrating wire 262 is advanced from the catheter to go from the coronary artery and penetrate into an adjacent coronary vein 264. An excess amount of the penetrating wire 262 is advanced into the coronary vein 264 to assist in retaining the penetrating wire within the coronary vein as the catheter is similarly advanced from the coronary artery 26 into the coronary vein 264. The position of the catheter 260 is then determined in the coronary vein 264 relative to the left ventricle 20. The catheter 260 is directed to orient the perforating wire 262 towards the myocardium 16 underneath the coronary vein 264 and to the left ventricle 20.

The perforating wire 262 creates an initial access port 268 through the vascular wall 272 of the adjacent coronary vein 264 and a second access port 270 in the exterior side 18 of the myocardium and completely through the myocardium 16 into the left ventricle 20. A valved conduit 266 is then inserted into and through the myocardium 16 creating a channel 42 directly from the left ventricle 20 to the coronary vein 264. The blood flow into the coronary vein 264 is limited to a particular area or section 286 by inserting plugs 274 within the coronary vein on both sides of the initial and second access ports 268, 270. The plugs 274 can be moved into their respective positions by insertion through the initial access port 268.

A second conduit 276 is inserted into the initial access port 268 to maintain a second channel 278 between the coronary artery 26 and the coronary vein 264. As a

result, blood flows during systole from the left ventricle 20 into the coronary vein 264 and subsequently into the coronary artery 26 distal to the blockage 28. The coronary vein 264 can provide a temporary reservoir of blood. The valved conduit 266 minimizes backflow of blood from the coronary vein 264 and artery 26 into the left ventricle 20 during diastole.

Another embodiment of this method is illustrated in Fig. 18. The initial access port 268 is offset in its alignment with the second access port 270A. The catheter 260 is guided to a location either a distance further distal or proximal to the initial access port 268 before the second access port 270A is created. Fig. 18 specifically illustrates a distal position.

The present invention includes still another percutaneous approach wherein transvascular and transmyocardial channels between the left ventricle and coronary artery extend to more than one blood source as illustrated in Fig. 19. An additional access port 280 is created between the coronary artery and the adjacent vein 264 proximal to the blockage 28 in the adjacent coronary artery 26. The catheter 260 is advanced through the interior of the coronary vein 264 to create the access ports 268 and 270. A third conduit 282 is inserted into the additional access port 280 to maintain the third channel 284. One of the plugs 274 is inserted into the coronary vein 264 in a proximal position to the additional access port 280.

It should be understood that the present invention provides for combining portions of different surgical approaches, different percutaneous approaches, or a combination of surgical and percutaneous approaches in one method. For example, a surgical approach can use a catheter in a method similar to that described with reference to Figs. 14 - 19. After gaining access to the exterior of the patient's heart and coronary vascular system, the same access area is used to guide the catheter to the coronary vascular system at a location which is significantly closer to the heart.

The present invention provides alternate methods of creating the access ports for the surgical and percutaneous approaches described above. Instead of dilating the access ports, a section of tissue can be removed to provide the channel through the myocardium or the vascular tissue. The diameter of the tissue section to be removed is preferably about equivalent to or larger than the diameter of the valved conduit to be inserted.

For example and not limitation, a section of tissue can be removed by mechanical means such as by positioning a rotary drill head or punch at the distal end 32 of the needle

assembly in Fig. 2 or the distal end of the delivery device 44 in Fig. 3. As the result, the dilation of the access port is partially or completely obviated.

Another suitable means for removing tissue is laser energy which is commonly used in transmyocardial revascularization (TMR) techniques with adjustments to make a larger diameter channel than is conventionally used in TMR. A laser can be used with either the surgical or percutaneous approaches described herein. The surgical approaches provide adequate space to align the laser from a position external to the heart and vascular system or the laser can be introduced into the left ventricle or coronary system and create a channel from the inside extending outward. A laser fiber can be carried by a guided catheter as described in the methods above.

The tissue removal means of the present invention provides channels which are self-maintaining. Channels created by the removal of tissue can avoid the use of a conduit to keep or maintain the channel open. As defined herein, the term self-maintained channel is a passageway through tissue which is open for blood flow from an oxygenated blood source to a selected site during at least a portion of the heart cycle, preferably during systole. With a self-maintaining channel, the regulation of blood is controlled by inserting only a valve, no conduit, into the channel. Or, the self-maintained channel can regulate the flow of blood naturally by orienting the self-maintained channel through the myocardium as described herein.

The conduits and valves of the present invention are made of natural vascular tissue or synthetic materials or a combination of both. The synthetic materials are bio-compatible and include metals, alloys and plastics containing one or more polymers. The conventional surgical polymers are suitable plastics. Metals or alloys which are not in themselves bio-compatible can be coated with a bio-compatible metal or plastic. Preferably, the conduit material is non-porous to blood. However, it is suitable to use material porous to blood and still provide blood flow completely through the length of the conduit.

A preferred synthetic conduit 400 is illustrated in Fig. 20 having an elongated body 402 with a cylindrical or tubular shape and a wall 404 having an exterior surface 406 and an interior surface 408. The wall 404 defines an interior space 410. The body 402 includes an inlet end 412 for receiving blood from the left ventricle or other oxygenated blood source and an outlet end 414 for delivering the oxygenated blood to a selected site such as a coronary artery or vein.

The preferred shape of the cross-section of the body 402 along its longitudinal axis 416 is circular. Other cross-sectional shapes are suitable for use by the present invention such as, for example and not limitation, triangular, rectangular, square, elliptical, oval, and other geometric or free-form shapes. The cross-sectional size is illustrated as uniform across the length of the body 402. However, the cross-sectional size can vary along the length, or taper or flare the body 402 near the ends 412 and 414 of the body 402.

The diameter of the conduit 400 is preferably not expandable, and the conduit is inserted into the channel 42 as a predetermined size without the need to expand the diameter of the body 402. The body 402 resists compressive forces placed on it by the myocardium during the heart cycle to maintain the channel 42 in the open position. However, the present invention also provides for using conduits with a diameter which is expandable after insertion into the myocardium.

Preferably, the length of the conduit 400 is sized to be longer than the maximum width the myocardium achieves during the heart cycle. The conduit 400 extends beyond the exterior side 18 and interior side 24 defining the myocardium and slightly into the left ventricle 20 and coronary artery 26. It is suitable to provide the length of the conduit 400 so that one end is approximately flush with the interior side 24 and/or exterior side 18 of the myocardium.

The conduit 400 includes projections 418 integrally formed with the body 402 near the inlet end 412 and outlet 414 means for retaining the conduit in position once it has been inserted within the myocardium 16 or other tissue layer. The projections 418 can have an end 420 which is barbed or otherwise shaped for slightly penetrating, embedding, or abutting the myocardium 16 in the area surrounding the ends 412 and 414. The connection between the body 402 and the projections 418 includes a spring bias which allows the projections 418 to fold relatively flat against the exterior surface 406 of the body while the conduit 400 is being inserted into the channel 42 through the myocardium 16 or tissue layer. The projections 418 then relax to their outwardly extended position once the ends 412, 414 of the conduit extend into the left ventricle 20 and coronary artery 26 and are clear of the channel 42. For example, the spring bias can be supplied by conventional memory or superelastic materials.

Preferably, the synthetic conduit 400 includes a valve 422 having flaps 424 which open to allow blood flow in one direction from the left ventricle 20 to the coronary artery

26 and close to minimize the backflow of blood in the reverse direction. The closure of the flaps 424 need not completely seal the interior space 410. The valve 422 can be supported by a ring 426 inserted within the interior space 410 so as to abut the interior surface 408 as a component separate from the body 402. Alternately, the valve 422 can be integrally formed with the wall 404.

Other examples of retaining means are provided by the present invention. For example and not limitation, Fig. 21 illustrates projections 430 which are initially retracted into the interior space 410 through slots 432 in the wall 404. The connection between the body 402 and the projections 430 includes a spring bias which allows the projections 430 to retract into the interior space 410 of the body while the conduit 400 is being inserted into the channel 42 through the myocardium 16 or tissue layer. The projections 430 are then released to their outwardly extended position once the conduit 400 is in the desired position. This embodiment also illustrates that the projections 430 slightly penetrate the face 434 of the channel 42 rather the area of the myocardium surrounding the channel.

Another example of the retaining means provided by the present invention include forming a screw thread 436 on the exterior surface 406 of the body as illustrated in Fig. 22. The thread 436 is of sufficient size and quantity to hold the conduit 400 in the desired position by biting into the face 434 of the channel. The thread 436 can extend over one or more sections of the exterior surface 406. The thread 436 need not be continuous and can be positioned anywhere along the length of the exterior surface 406.

Other examples of the retaining means provided by the present invention include expanding one or both ends of the conduit 400 to a diameter greater than the channel 42. Fig. 23 illustrates the inlet end 412 being flared 438 so that its diameter is greater than the diameter of the channel 42. The flared end 438 extends beyond the myocardium 16 layer. The end 438 can be flared prior to or after insertion of the conduit 400 into desired position. Fig. 24 illustrates the inlet end 412 being effectively expanded by a coating 440 applied to the exterior surface 406 of the conduit near the end. The coating 440 expands after insertion 440A to hold the conduit 400 in the desired position. There are several known plastics or foams which exhibit predictable expansion properties which are suitable material for use as the coating 440.

In similar embodiments, an adherence between the exterior surface 406 of the conduit and the face of the myocardium along the channel can be promoted to retain the conduit in the desired position. For example, at least a portion of the length of the

conduit 400 can be coated on the exterior surface 406 with a bio-compatible adhesive which assists the adherence with the face of the myocardium. Another example is to abrade the exterior surface 406 of the conduit.

Fig. 25 illustrates that the retaining or anchoring means can be located anywhere along the length of the body 482 of the conduit 480 such as the middle section 484. Another type of anchoring means is also illustrated in the form of elongated slots 486. By having comparable sizes in the diameters of the conduit 480 and the channel, the face of the myocardium along the channel may embed into the areas of the slots 486 to retain the conduit in the desired position.

The retaining means can also be useful in sizing the length of a conduit immediately after insertion through the myocardium. For example, using the surgical approach described in reference to Fig. 4, a conduit having a length significantly longer that the myocardium's maximum width can be inserted through the coronary artery and into the myocardium. Preferably, the end of the conduit extending into the left ventricle includes a retaining means. Once the resistance of the retaining means is felt by attempting to withdraw the conduit, the excess length of the conduit extending out of the myocardium and through the coronary artery is cut off.

The conduit 400 with valve 422 of the present invention preferably adjusts to the changing width of the myocardium 16 during the heart cycle. Figs. 26A and 26B illustrate another example of the conduit 400 provided by the present invention wherein the inlet end 412 is flared 438 and the outlet end 414 has projections 442 which slightly penetrate into the area of the myocardium 16 surrounding the channel 42. During systole, the thickness of the myocardium 16 is near its greatest during the heart cycle. As illustrated in Fig. 26A, the outlet end 414 of the conduit extends slightly into the coronary artery 26 and is retained in position by being anchored to the exterior side 18 of the myocardium. The length of the conduit 400 is predetermined so that the inlet end 412 of the conduit also extends slightly into the left ventricle 20 when the myocardium 16 is thickest during the heart cycle. Optionally, the inlet end 412 can be flared 438 so as to further assure retaining the interior side 24 of the myocardium to provide at least a slight extension of the inlet end 412 into the left ventricle 20. During diastole, the thickness of the myocardium 16 decreases. As illustrated in 26B, the outlet end 414 is anchored on one side of the conduit allowing the remainder of the myocardium to slide along the

longitudinal axis 416 of the conduit. The inlet end 412 is not specifically anchored and is free to extend further into the left ventricle 20 during diastole.

The present invention provides other means for adjusting the conduit 400 to the changing width of the myocardium 16 during the heart cycle. Fig. 27 illustrates the conduit 400 with at least a two telescoping components 444, 446 which slidably insert into one another as indicated by arrow 445. Both the inlet end 412 and the outlet end 414 retain the myocardium in the desired position by anchoring the ends with projections 442 to the interior side 24 and exterior side 18 of the myocardium, respectively. As the heart cycles, the component 446 slides within component 444 in a telescoping manner to adjust to the changing thickness of the myocardium. The length of the telescoping components 444, 446 are predetermined so that they remain within each other all through the heart cycle.

Other examples of means for adjusting the conduit 400 to the changing width of the myocardium 16 during the heart cycle include the illustration in Fig. 28 which provides the conduit 400 with an accordion section 456 which expands and contracts in a longitudinal direction as indicated by arrow 457 while providing resistance against radial compression. Each end 412 and 414 retains the myocardium in the desired position by anchoring the ends with projections 442 to the interior side 24 and exterior side 18 of the myocardium, respectively. As the heart cycles as indicated by arrow 452, the two ends 412, 414 move towards each other during diastole and away from each other during systole with the accordion section 456 respectively contracting and expanding in a longitudinal direction.

Alternately, Fig. 29 illustrates another accordion section 458 which reversibly expands in a latitudinal direction. Each end 412 and 414 retains the myocardium in the desired position by anchoring the ends with projections 442 to the interior side 24 and exterior side 18 of the myocardium, respectively. As the heart cycles, the two ends 412, 414 move towards each other during diastole and away from each other during systole with the accordion section 458 respectively contracting and expanding in a latitudinal direction as indicated by arrows 460. The latitudinal accordion section 458 not only maintains and regulates blood flow through the channel, but also provides a temporary reservoir of blood in the accordion section 458 itself. The valve 422 can be placed at either end 412, 414 or valves placed at both.

Another example of the adjusting means of the present invention is illustrated in Fig. 30 wherein the conduit 400 includes at least two components 448, 450 which form a body 402 which is discontinuous. The ends 412 and 414 retains the myocardium 16 in the desired position by anchoring the ends with projections 442 to the interior side 24 and exterior side 18 of the myocardium, respectively. The valve 422 can be included in either component 488 or 450. With the components 448, 450 positioned perpendicular to the myocardium width, the two components 448, 450 move towards each other during diastole and away from each other during systole when the heart cycles as indicated by arrow 452. Without support from either component 448, 459, a section 454 of the channel between the two components 448, 450 is self-maintained in the open position.

Fig. 31 illustrates an example of an adjusting means wherein the conduit 400 includes a body 402 made of a continuous coil 462 which expands and contracts along its longitudinal axis to accommodate the changing thickness of the myocardium 16 during the heart cycle while resisting radial compression. The outer periphery 464 of the coil 462 slides along the face 466 of the myocardium defining the channel 42. The coil 464 is anchored to the myocardium 16 at the inlet end 468 and outlet end 470 by projections 472 which are supported by rings 474 connecting to respective ends of the coil 464. As the coil 462 expands, gaps 476 are formed between the outer periphery 464 of individual spirals or the gaps 476 increase in size if the gaps already exist when the coil 462 is at its maximum level of relaxation during systole. Should the face 466 of the myocardium adhere to the outer periphery 464 of one or more individual spirals, either immediately after insertion into the channel or as a long-term effect, the remaining spirals provide expansion by moving along the longitudinal axis.

The present invention provides conduits with a variety of configurations emphasizing a non-obtrusive, non-traumatic connection into the coronary artery. As illustrated in Fig. 32, a T-shaped conduit 490 includes a branch 492 allowing the continued flow of blood or prevents the stasis of blood proximal to the conduit in the coronary artery 26. Fig. 33 illustrates a hook-shaped conduit 494 having a right-angle bend toward the direction of desired blood flow. The outer periphery 496 of the conduit outlet end can be sized to have the coronary artery dilated over its edge or can be smaller than the diameter of the coronary artery. Fig. 34 illustrates a hybrid, synthetic/natural conduit 497 which includes a section of vascular tissue 498 attached to a synthetic segment 499. The vascular tissue 498 is attached at 495 to the wall 493 of the coronary

artery by conventional closure means such as suturing. In this embodiment, no section of the conduit 497 extends into the coronary artery.

The present invention also provides a naturally valved conduit such as a vein or other vascular tissue which is preferably autologous. A conduit made from the vein can be all natural or include synthetic materials in combination with the vein. As illustrated in Fig. 35, a preferred combination conduit 500 combines a vein 502 which is at least partially supported by a synthetic cage 504 having an elongated body 506 with a cylindrical or tubular shape and longitudinal members 508 having an exterior surface 510 and an interior surface 512. The cage 504 defines an interior space 514. The body 506 includes end members 516 connected to the longitudinal members 508. The cage 504 includes projections 518 which, as previously described, retain the conduit 500 in the desired position within the myocardium.

The vein 502 is extended along the interior surface 512 through the interior space 514 of the conduit. The ends 520 of the vein 502 are stretched over end members 516 and back in the reverse direction to secure the vein 502 to the cage 504. Optionally, a suture can be placed through the end 520 and the wall 528 of the vein. The vein 502 defines an inlet end 522 for receiving blood from the left ventricle or other oxygenated blood source and an outlet end 524 for delivering the oxygenated blood to a selected site such as a coronary artery or vein.

The present invention regulates the flow of blood through the conduit 500 utilizing the flaps and wall movement of the vein which are inherent, natural properties of the vein 502. The natural valving function of the vein 502 is preserved by allowing the wall 528 of the vein to move towards itself or substantially collapse upon itself as indicated by arrows 526.

Another embodiment of the combination conduit 500 is illustrated in Fig. 36. The cage 504 includes a second pair of end members 530 spaced in a parallel relationship to the end members 516 and connected to the longitudinal members 508. Each end 520 of the vein 502 is inserted in a press fit between one of the end members 516 and second end members 530 to secure the vein 502 to the cage 504. Other means of securing the vein 502 to the cage 504 are also suitable such as suturing the ends 520 of the vein to the end members 516 with a continuous suture or a plurality of individual sutures. Fig. 36 also illustrates another example of positioning the vein 502 along the exterior side 510 of the

cage. As indicated in phantom at 528A, the wall 528 moves toward itself or substantially collapses upon itself to preserve the natural valving of the vein 502.

The present invention provides other types of valves for regulating the flow of blood through a conduit or a self-maintained channel. One valve type, as used in the Examples herein, is similar to a Starling resistor and illustrated in Fig. 37. The conduit 550 includes a rigid, elongated body 552 having an inlet end 554 which extends into the left ventricle 20. The body 552 extends substantially through the myocardium 16. On the outlet end 556 of the body is attached a valve 558 having a tubular body 560 made of a pliable material which extends into the coronary artery 26 distal to the blockage 28. The pliable material can be a section of vein. The tubular body 560 is sufficiently flexible to collapse on itself. During systole, blood flows out of the outlet end 556 into the coronary artery. As the cycle of the heart approaches diastole, the pressure of the blood flowing from the outlet end 556 decreases to the point where the pliable body 560 collapses which minimizes the reverse flow of blood from the coronary artery 26 back into the left ventricle 20. Optionally, a cage 548 can be inserted into the coronary artery 26 in the area of the tubular body 560 to assist in preventing the collapse of the artery in that area.

Another example of the valves provided by the present invention is illustrated in Figs. 38A and 38B. A conduit 560 extends completely through the myocardium 16 and slightly into the left ventricle 20 and the coronary artery 26. The conduit 560 includes at least one segment 562 that is made of a pliable material which resists compression by small radial forces but which collapses as seen in Fig. 38B during a portion of the heart cycle. The conduit 560 is orientated at an obtuse angle to the interior side 24 and exterior side 18 of the myocardium and to the direction of change in the thickness of the myocardium. Because of the conduit's 560 orientation within the myocardium 16, the forces applied by the surrounding myocardium as it contracts and relaxes during the cycle of the heart change the both the length and diameter of the conduit 560 as generally illustrated in Fig. 38B. As a result, the flow of blood is minimized into the left ventricle 20 during the cycle of the heart.

As described above, the present invention provides a self-maintained channel 600 defined by a face 602 of the myocardium 16 as illustrated in Fig. 39. The channel 600 extends completely through the myocardium 16 in a perpendicular direction from the left ventricle 20 on the interior side 24 to the coronary artery 26 on the exterior side 18. The

channel 600 is created by removing tissue so that it remains at least partially open during the cycle of the heart.

Preferably, the self-maintained channel 600 includes a valve 604 inserted within the channel as illustrated in Figs. 39 and 40. The valve 604 includes interleaved flaps 606 supported on a body 608. The valve 604 is not associated with a conduit. The width of the body 608 is preferably the minimum size required to provide support and orientation for the flaps 606 and not particularly to maintain the channel 600 open. The flaps 606 are set to open during positive pressure exerted by blood flow in the direction from the left ventricle 20 to the coronary artery 26. Negative pressure or blood flow in the reverse direction at least partially closes the flaps 606 to minimize the flow of blood to the left ventricle 20.

The body 608 includes a periphery 610 having a thread 612 integrally formed along the periphery. The thread 612 includes a starting edge 614 for engaging the face 602 and slightly dilating the diameter of the myocardium 16. As the periphery 610 is rotated, the starting edge 614 assists the advance of the thread 612 into contact with the face 602 of the myocardium. The thread 612 can slightly embed itself or slightly penetrate into the face 602 of the myocardium to retain the valve 604 in the self-maintained channel 600.

Another example of a mechanical means for regulating blood flow is to use a material in place of the flaps 606 which is semi-permeable to blood flow. The semi-permeable material can allow the blood to flow from the left ventricle while minimizing the reverse flow of blood.

The present invention also provides self-maintained channels which regulate the flow of blood without a synthetic valve as illustrated by the examples in Figs. 41 and 42. Self-maintained channel 620 extends completely through the myocardium 16 from the left ventricle 20 to the coronary artery 26. The channel 620 includes two segments 622 and 624 which are orientated at an obtuse angle to the interior side 24 and exterior side 18 of the myocardium, respectively. A third segment 626 connects to the other segments 622, 624 and is orientated in a generally parallel direction relative to the sides 24, 18 of the myocardium and a perpendicular direction to the change in the thickness of the myocardium. Because the orientation within the myocardium of the two segments 622, 624 and third segment 626 are different, each of the segments is affected differently by forces applied by the surrounding myocardium as it contracts and relaxes during the cycle

of the heart. The forces from the myocardium can change both the length and diameter of the segments 622, 624, and 626. As a result, the flow of blood is minimized into the left ventricle 20 during the cycle of the heart. It should be noted that arrows indicate only a general movement of the myocardium 16 in changing thickness during the heart cycle. There are forces experienced during the heart cycle within the myocardium 16 which are not strictly orientated perpendicular to the coronary artery and left ventricle.

Another example of a self-maintained channel which regulates the flow of blood therethrough with the natural rhythmic cycle of the heart is illustrated in Fig. 42. The self-maintained channel 640 includes a bowed or curved configuration which extends completely through the myocardium 16 from the left ventricle 20 to the coronary artery 26. With proper orientation of the bowed configuration between the interior side 24 and exterior side 18 of the myocardium, the forces applied by the surrounding myocardium as it contracts and relaxes during the cycle of the heart can be advantageously used to regulate the flow of blood through the channel 640. The forces from the myocardium can change both the length and diameter of the channel 640. As a result, the flow of blood is minimized into the left ventricle 20 during the cycle of the heart.

EXAMPLES

Two sets of experiments utilizing animals were designed to evaluate the acute functionality of the inventive methods. Each experiment was performed on a beating heart. No type of temporary assist or heart-lung bypass technique was utilized. Anesthesia was maintained with oxygen administration in accordance with conventional protocol. ECG was monitored and an arterial monitoring catheter was placed in the left internal mammary artery for assessment of blood pressure.

The first set of experiments was carried out on seven female Yorkshire pigs weighing 30-35 kg. On four of the pigs, a formal sternotomy was used and in the other three pigs, a left anterior 4th intercostal space thoracotomy was used. A prototype conduit was introduced into the left ventricle through a formal sternotomy with the other end of the conduit introduced into the left anterior descending coronary artery through cannulation. The left anterior descending coronary artery was then tied proximally. In this set of experiments, blood flow was delivered to the proximally occluded left anterior descending artery from the left ventricular chamber through a valved conduit, there being no other blood supply to the left anterior descending coronary artery.

Several different types of inventive valves were incorporated within the conduit. These valves consisted of a fine penrose tube or an IMA vein suspended between two ports in a chamber which could be pressurized. The IMA vein would be harvested shortly before and have about a 2 cm length with one or two valves. When connected in this fashion, blood passed in a continuous path from the left ventricular chamber via the penrose tube or vein into the left anterior descending coronary artery. The surrounding chamber could then be pressurized to any pre-determined level and in this way, the penrose tube or vein would collapse and prevent backflow when left ventricular pressure fell below the pressurized chamber level. The penrose tube or vein functioned in a manner commonly referred to as a "Starling resister" similar to that illustrated in Fig 20.

Another valve type employed a small penrose tube or a vein segment which was suspended from only one port in a non-pressurized chamber with a second opening in the chamber allowing continuity of blood flow from the left ventricle to the left anterior descending artery. Each harvested vein graft was inserted between the two catheters, creating a valved conduit approximately 15mm long with an overall length of about 10 cm for complete external pathway. In this embodiment, any attempt at backflow of blood to the left ventricular chamber would cause collapse of the penrose tube or vein segment and occlude the backflow port.

In the seven pigs, Doppler flow measurement revealed both systolic and some diastolic flow in the left anterior descending coronary artery. Blood flow was confirmed by miniature Doppler on the distal coronary and vein graft and the flow pattern was about 80% systolic and 20% diastolic There was no obvious demarcation of an ischemic zone distal to the left anterior descending coronary artery ligation nor were arrhythmias or an observable decrease in left ventricular contraction noted. The inventive conduit was left in place from 30 min. to 1 and ½ hours.

With occlusion of the conduit carrying blood from the left ventricular chamber, all of the hearts fibrillated within 3-5 minutes. This result indicated that the ventricular supply of coronary blood was essential and provided for normal function for the duration of the experiment.

The second set of experiments was designed to evaluate the net coronary flow per minute whether delivered in systole or diastole, under control conditions and compared these to the net coronary flow in mL/min delivered from the left ventricle as the only source (all proximal coronary arteries having been ligated.) In this set of experiments six

Yorkshire pigs weighing 30-35 kg underwent surgical sternotomy and cannulation of the coronary sinus - the common outflow of all coronary blood flow. The left hemiazygous vein was ligated so that coronary sinus blood was not contaminated by the systemic circulation. Under control conditions all blood flow emanating from the coronary sinus was collected for a specific period of time and the mL of coronary blood flow per minute calculated. A left ventricular conduit was then surgically inserted into the left ventricular chamber from the epicardial surface and then connected to cannulas which had been inserted into the left and right coronary os. When the left main coronary artery and the right coronary artery were snared around the introduced cannula the left ventricle was the only source for coronary blood flow. In this experimental set-up, coronary blood flow therefore originated from the left ventricle and passed through a prototype conduit and valving system as described above into the right coronary os and left coronary os. Measurement of total coronary blood flow emanating from the coronary sinus under this condition demonstrated no difference in net coronary blood flow per minute from the control condition. With the coronary artery ligated, net coronary blood flow per minute originating from the left ventricular chamber via the inventive conduit was also measured without a valve in place. These sets of experiments demonstrated that net coronary blood flow per minute was similar whether delivered via the aortic root under control conditions or from a left ventricular source via the inventive conduit.

Several clinical discoveries were made which further support the physiologic viability of the inventive methods. There is a similarity of physiology to patients with Aortic Valve Insufficiency. The delivery requirements per beat are very small. Continuous flow is observed during coronary angiograms. The mean pressure within the myocardium is relatively low compared to systolic perfusion pressure. The animals experienced no change in EKG and no change in heart wall motion. There was no change in flow characteristics of blood. The coronary arterial system was compliant and enabled diastolic perfusion.

Some conclusions may be drawn from other observations. The dynamic motion of heart muscle and subsequent motion of the conduit may reduce stasis which contributes to clot formation. The high velocity of delivery from the left ventricle to the coronary artery may reduce incidence of clot formation and resulting thrombosis (occlusion). The short length of the conduit (approximately 15mm) may reduce the chance of clot formation and thrombosis (occlusion).

In comparing the inventive left ventricle to coronary artery approach to the conventional coronary perfusion approach, it was found that the same amount of blood was being delivered across the myocardium to the coronary sinus in both approaches. Compared to conventional transmyocardial revascularization techniques the present invention used much larger holes, enabled patency of the channel and demonstrated the heart's ability to tolerate this type of intervention with little effect.

The present invention provides significant advantages when compared to the prior art relating to interventional procedures such as the ability to improve long term patency rates and reduce the high rate of retreatment. Furthermore, the present invention allows multiple vessels to be treated. Compared to CABG surgery, the present invention is a less-invasive procedure which can be performed on a beating heart using smaller incisions for entry than normally required by conventional techniques. Also, harvesting an autologous graft may not be needed.

The present invention fulfills many needs found wanting in the prior art. Many patients were not candidates for percutaneous or CABG surgery because they could not be fully revascularized by the surgery. The present invention significantly enlarges the population of potential candidates. Furthermore, the use of small ports between the ribs to provide the revascularization provides an access site in the immediate vicinity of the selected site in the arterial vascular system and avoids the use of a sternotomy and/or a thoracotomy. The present invention provides access to the arterial vascular system on both sides of the heart such as the left anterior descending artery, circumflex artery, and their tributaries.

As described, the present invention fulfills many clinical needs that are currently unmet by the prior art. For example, many patients with coronary artery disease are not amenable to CABG or percutaneous treatment due to their extensive disease. However, this invention offers a comparable treatment alternative to conventional techniques allowing these patients to receive care. Furthermore, the inventive approach provides methods and devices that allow for coronary revascularization procedures to be performed through small holes instead of a chest incision. The present invention provides access to the arterial vascular system allowing for all vessels of the heart to be revascularized.

The present invention also provides for partial revascularization or increased flow by having a self-maintained channel or conduit without a valve. In this embodiment, a

channel is created and maintained between an oxygenated blood source and a site selected in the arterial vascular system. The channel does not incorporate means for regulating the blood flow therethrough. More particularly, when the selected site is distal to a substantial or complete blockage or occlusion, a self-maintained channel or conduit without a valve between the left ventricle and selected site provides significant, but not complete, revascularization of the selected site and the surrounding area.

WHAT IS CLAIMED IS:

1. A method for providing blood flow to a patient's coronary artery, the method comprising steps of:

(a) positioning a guide member so that a portion of the guide member extends into a source of oxygenated blood;

(b) using the guide member to introduce a device into the source of oxygenated blood, the device being configured to create a channel for blood flow from the oxygenated blood source to the coronary artery; and

(c) using the device to create a channel for blood flow from the oxygenated blood source to the coronary artery.

2. The method of claim 1, further comprising perforating and dilating tissue surrounding the blood source to create the channel therein.

3. The method of claim 1, further comprising removing tissue to form an aperture completely through tissue surrounding the blood source to partially create the channel therein.

4. The method of claim 1, wherein steps (a), (b) and (c) are carried out while exposing at least a portion of the patient's heart for surgical access.

5. The method of claim 1, wherein the device is a conduit and steps (b) and (c) are carried out by using the guide member to deliver the conduit into the oxygenated blood source and position the conduit in tissue to create the channel.

6. The method of claim 1, wherein the device is a conduit delivery device that supports a conduit and steps (b) and (c) are carried out by using the guide member to place the conduit delivery device in the oxygenated blood source and position the conduit in tissue to create the channel.

7. The method of claim 1, wherein the device is used to remove a section of tissue to form the channel.

8. The method of claim 1, wherein the blood source is the left ventricle and the channel is formed in the myocardium.

9. The method of claim 8, wherein step (a) is carried out by first passing the guide member through the myocardium into the left ventricle, and then passing the guide member from the left ventricle into the coronary artery.

10. The method of claim 1, wherein the guide member is a guide wire and a hollow needle is used to position the portion of the guide wire in the oxygenated blood source.

11. The method of claim 10 wherein the needle has a flashback lumen to indicate entry of the needle into the source of oxygenated blood or the coronary artery.

12. The method of claim 1, further comprising creating a channel that provides the coronary artery with blood from two sources of oxygenated blood.

13. The method of claim 1, further comprising creating a channel that delivers blood to more than one site in the coronary artery.

14. The method of claim 1, wherein step (b) is carried out by positioning a non-expandable conduit that communicates the coronary artery with the oxygenated blood source.

15. A method for placing a coronary artery in flow communication with a source of oxygenated blood, the method comprising steps of:

(a) passing a conduit delivery device through the wall of a coronary artery into the lumen of the coronary artery, wherein the lumen of the artery is at least partially occluded by an obstruction and the device is adapted to establish a blood flow path;

(b) passing the conduit delivery device from the lumen of the coronary artery into tissue located adjacent a source of oxygenated blood; and

(c) using the conduit delivery device to position a conduit that creates a blood flow path from the oxygenated blood source to the coronary artery distal to the obstruction.

16. The method of claim 15, wherein the conduit delivery device is coupled to a guide wire, and step (c) is carried out by using the delivery device to position a rigid, non-expandable conduit in the myocardium.

17. The method of claim 15, further comprising maintaining the channel in an open position for blood flow through both the diastolic and systolic phases of the heart cycle.

18. A method for performing a coronary revascularization procedure to bypass an obstruction in a coronary artery, the method comprising steps of:

(a) providing a conduit at least partially covered by a sheath, the conduit adapted to establish a blood flow path between a source of oxygenated blood and a lumen of a coronary artery that is at least partially occluded by an obstruction;

(b) passing the conduit and sheath into tissue adjacent the source of oxygenated blood or the coronary artery to position the conduit at a desired location in the tissue; and

(c) removing the sheath.

19. The method of claim 18, wherein the source of oxygenated blood is the left ventricle and the conduit is placed in the myocardium.

20. The method of claim 19, wherein the conduit and sheath are moved into the left ventricle and then passed outwardly through the myocardium to position the conduit at the desired location.

21. The method of claim 19, wherein the conduit and sheath are passed through the wall of the coronary artery and then moved inwardly into the myocardium to position the conduit at the desired location.

22. The method of claim 18, further comprising regulating the blood flow in the conduit to minimize blood flow from the coronary artery to the blood source during the diastolic phase of the heart cycle.

23. A method for placing a coronary artery in communication with a source of oxygenated blood, the method comprising steps of:

(a) forming an opening in the wall of a coronary artery; and

(b) forming an opening in tissue that communicates the lumen of the coronary artery with a source of oxygenated blood;

withdrawal of the delivery device 44, the balloon 36 at the distal end 34 of the guide wire is deflated (or the temporary anchor means is retracted) allowing withdrawal of the guide wire 30 from the coronary artery 26 along the valved conduit 48 and from the left ventricle 20 through the initial access port 14. The initial access port 14 is then sealed with a suture or allowed to seal itself without assistance.

Referring to Fig. 1, another embodiment of the present invention effectively anchors the distal end of the guide wire by initially continuing to advance the guide wire beyond the coronary artery 26. As shown in phantom, the distal end 34A of the guide wire is advanced through the interior 70 and exiting from the exterior side 72 of the coronary artery. The distal end 34A is then exposed for anchoring in position.

The needle assembly 12 can be of any shape sufficient to perforate and penetrate the myocardium 16 while minimizing tissue damage. For example, Fig. 1 shows the needle assembly 12 having a curved shape which can assist in initially penetrating from the exterior side 18 of the myocardium and continuing to penetrate the interior side 24 of the myocardium underneath the coronary artery 26. Other shapes for the needle assembly 12 are suitable for use in the present invention which can penetrate and can depend upon the particular surgical approach to be used. For example and not limitation, Fig. 2 illustrates a straight needle assembly 12, commonly referred to as a seldinger-type needle. A suitable diameter for the needle component 40 is about 12 gauge.

Fig. 2 specifically illustrates more details of the needle assembly 12 . Preferably, the needle assembly 12 includes a needle component 40 having at least one lumen 54 extending substantially across the length of the needle component. The first lumen 54 can be used to allow blood flow therethrough. As the distal end 32 of the needle assembly is advanced from the myocardium exterior 18 and enters the left ventricle 20, the blood in the left ventricle 20 will travel through the lumen 54 and blood 66 will be visually observed exiting the proximal end 62 of the needle assembly. This bleeding "flashback" 66 is especially prominent during the contraction of the left ventricle 20. As the distal end 32 of the needle assembly is further advanced through the left ventricle 20 to contact the myocardium interior 24, the bleeding flashback 66 will subside until the distal end 32 of the needle assembly completely penetrates the myocardium 16. The entry of the distal end 32 of the needle assembly into the coronary artery 26 will be evidenced by resumption of the bleeding flashback 66 through the proximal end 62 of the

needle component or some other accessing feature. The first lumen 54 is also used to retractably carry the guide wire 30 therethrough.

Optionally, the assembly 12 can include a second lumen 56 which also extends substantially across the length of the needle component 40. One end 58A of the second lumen is located at the distal end 32 of the needle component. Alternately, the end 58B of the second lumen is located at some predetermined distance from the distal end 32 of the needle component. The other end 60 of the lumen is located near the proximal end 62 of the needle component. As the distal end 32 of the needle assembly is advanced from the myocardium exterior 18 and enters the left ventricle 20, the blood in the left ventricle 20 will travel from one end 58A or 58B of the second lumen to the other end 60 and blood 66 will be visually observed exiting the proximal end 62 of the needle assembly.

The lumen 54 or second lumen 56 and its ends 60 and 58A or 58B act as marker ports which provide evidence when the distal end 32 of the needle assembly is first in the left ventricle 20 and subsequently in the coronary artery 26. Other means for marking the position of the distal end 32 of the needle assembly are suitable for use with the present invention. For example and not limitation, the depth of the penetration through the myocardium to form the initial and second access ports 14 and 22 can be estimated by conventional diagnostic imaging and/or by reading one or more depth markers 64 placed in predetermined positions along the length of the needle assembly 12.

The needle assembly 12 provides for perforating the myocardium 16 to create an access port. The assembly 12 also provides for dilating the access port and for ensuring the position of the assembly has been advanced into the left ventricle 20 and/or coronary artery 26.

Another inventive method is a surgical approach which gains access to the exterior of the patient's heart illustrated in Fig. 4 through conventional cardiac surgical methods. Using the needle assembly 12 as previously described in Fig. 2, an initial access port 76 is made in the coronary artery 26 distal to the point of the obstruction 28. The needle assembly 12 is advanced into and through the coronary artery 26 to contact the exterior 18 of the myocardium underneath the coronary artery 26. The needle assembly 12 is further advanced to penetrate the myocardium 16 and make an access port 78 in the myocardium while eventually entering the left ventricle 20. The needle assembly 12 extends into the left ventricle 20 to the extent that flashback bleeding 66 is observed to assure the myocardium 16 has been completely penetrated.

After the needle assembly 12 has created the second access port 78, a guide wire 30 or other directional means is extended from the distal end 32 of the needle assembly into the left ventricle 20. A sufficient length of the guide wire 30 is advanced into the left ventricle 20 to prevent its premature withdrawal. Optionally, the distal end 34 of the guide wire can contain an inflatable balloon 36 or other temporary anchoring means to prevent premature withdrawal of the guide wire 30 from the left ventricle 20. With the guide wire 30 extending from the left ventricle 20 to the exterior 18 of the myocardium underneath the coronary artery 26, through the interior 70 of the coronary artery and to the exterior 72 of the coronary artery, the needle component 40 of the assembly is withdrawn from both the access ports 78, 76.

In another embodiment of this surgical approach wherein the initial access port 76 is created in the exterior of the coronary artery 26, it may be desirable to offset the alignment of the initial access port shown as 76A from the myocardium access port 78. This can be accomplished in several ways such as through simple angling of the needle assembly 12 while creating the access ports or using a needle assembly 12 which is curved or has an offset in its configuration. The eventual closing of the initial access port 76 may cause trauma to the vascular tissue in that area. Providing an offset in the alignment of the access ports 76A, 78 avoids the initial access port area from being directly over or along the path of the blood flow path from the inserted valved conduit 48.

Similar to what has been discussed before, the access port 78 in the myocardium is dilated to accommodate the delivery of a valved conduit 48 therein. Inserting the valved conduit 48 into the access port 78 creates and maintains by mechanical means a channel 42 through the myocardium from the left ventricle 20 to the coronary artery 26. The delivery of the valved conduit 48 can be effectuated by inserting a guide wire 30, withdrawing the needle assembly 12, directing a delivery assembly 44 as seen in Fig. 3 containing the valved conduit 48 over the guide wire 30 through the initial access port 76 to the access port 78, dilating the access port 78, inserting the valved conduit 48 into the access port 78, and withdrawing the delivery assembly 44 and guide wire 30 from the left ventricle 20 and coronary artery 26. Subsequently, the initial access port 76 on the exterior 72 of the coronary artery is closed by stitches, staples, or other closure means.

An alternate embodiment of the present invention employs a needle assembly and delivery assembly which are integrated so that the guide wire is eliminated. The integrated assembly provides sufficient dilation of the respective access ports to deliver

the valved conduit therein. For example, as illustrated in Fig. 5, an integrated assembly 80 includes a perforating distal end 82 with a series of gradations or steps 84 for gradually dilating the respective access port as the integrated assembly 80 is further advanced. The steps 84 can be pre-formed or result from a retractable telescoping of the body 86 of the integrated assembly which can gradually vary its diameter. The valved conduit 48 is then removed from the body 86 with a pusher rod 88 and the integrated assembly 80 inserts the valved conduit 48 into the access port 78 so that the valved conduit 48 extends through the myocardium 16 from the left ventricle 20 to the coronary artery 26. The conduit 48 keeps the access port 78 dilated and maintains the channel 42 between the left ventricle 20 and the coronary artery 26.

Still another inventive method is a surgical approach which gains access to the exterior of the patient's heart and coronary vascular system 10 illustrated in Fig. 6 through conventional cardiac surgical methods. Using a first integrated needle/delivery assembly 90, an access port 92 is created through the myocardium 16 from the exterior side 18 into the left ventricle 20. Similar to the previous description herein, the distal end 98 of the integrated needle assembly perforates the myocardium and the myocardium access port 92 is dilated to accommodate the delivery of one end 96 of the valved conduit 94 which is advanced into the myocardium access port 92. Inserting the end 96 of the valved conduit into the myocardium access port 92 creates and maintains a channel through the myocardium 16 from the left ventricle 20 into one end 96 of the valved conduit.

Using a second needle/delivery assembly 100, an artery access port 102 is made in the exterior side 72 of the coronary artery. With surgical access to the artery access point 102, the second integrated needle/delivery assembly 100 can immediately dilate the artery access port 102 and insert the other end 104 of the valved conduit after the integrated needle/delivery assembly 100 perforates the coronary artery 26. Inserting the other end 104 of the valved conduit into the artery access port 102 creates and maintains a channel 42 from the left ventricle 20 into one end 96 of the valved conduit, out the other end 104 of the valved conduit, and into the coronary artery 26.

The first needle/delivery assembly 90 is more specifically illustrated in Fig. 7 which includes a body 106 made of a flexible material. The body 106 is perforated along its longitudinal axis to form seams 108. The valved conduit 94 extends along the longitudinal axis of the body 106 with the end 96 of the valved conduit positioned near

the distal end 98 of the assembly and the other end 104 of the valved conduit exiting from the proximal end 110 of the assembly. Once the assembly 90 has perforated and dilated the myocardium access port 92, gripping the other end 104 of the valved conduit exiting from the assembly 90 can be helpful in either advancing the end 96 of the valved conduit into the myocardium access port 92 or holding the end 96 of the valved conduit within the myocardium access port 92 as the remainder of the assembly 90 is withdrawn. To ease the withdrawal of the assembly 90 from the myocardium access port 92, the perforations are broken apart to split the seams 108 and the longitudinal sections 112 and 114 of the body 106 are peeled away leaving the end 96 of the valved conduit in the myocardium access port 92.

In one alternate embodiment of the type of valved conduit that can be used with this surgical approach, the valved conduit 94 can have two separate conduit sections wherein a first conduit section 118 is inserted in the myocardium access port 92 and a second conduit section 119 is inserted in the artery access port 102. Subsequently, the two sections are connected together to form a continuous channel for the blood flow from the left ventricle 20 to the coronary artery 26. The valve 116 can be integrally positioned in either the first or second conduit section. Or, the valve 116 can be a separate piece from the two conduit sections wherein each conduit section connects to opposite sides of the valve.

In another embodiment of this surgical approach, delivery of either end 96 or 104, or both ends, of the valved conduit 94 can be effectuated by inserting a guide wire through a needle assembly as illustrated in Fig. 2 into the left ventricle 20, withdrawing the needle assembly, directing a delivery assembly as illustrated in Fig. 3 containing the valved conduit 94 over the guide wire to the myocardium access port 92, dilating the myocardium access port 92, inserting one end 96 of the valved conduit into the myocardium access port 92, and withdrawing the delivery assembly and guide wire from the left ventricle 20.

A further inventive method is a surgical approach which directly accesses and exposes the outside of the patient's heart and coronary vascular system illustrated in Fig. 8. Using a first needle/delivery assembly 120 of similar design to the one illustrated in Fig. 7, a myocardium access port 122 is made in the myocardium 16 from the exterior side 18 into the left ventricle 20. The myocardium access port 122 is dilated to accommodate the delivery of a first input end 124 of a Y-shaped, multi-branched valved

conduit 126 therein. Inserting the first input end 124 of the valved conduit into the myocardium access port 122 creates and maintains a channel through the myocardium 16 from the left ventricle 20 into a first input end 124 of the conduit.

Using a second needle/delivery assembly 128, a distal artery access port 130 is made in the exterior side 72 of the coronary artery at a point distal to the lesion or blockage 28. With surgical access to the distal artery access port 130, the second assembly 128 can immediately dilate the distal artery access port 130 and insert an output end 132 of the multi-branched conduit after the second assembly 128 perforates the coronary artery 26.

Using a third needle/delivery assembly 134, a proximal artery access port 136 is made in the exterior side 72 of the coronary artery at a point proximal to the obstruction or blockage 28. With the surgical access to the proximal artery access point 136, the third assembly 134 can immediately dilate the proximal artery access port 136 and inserts a second input end 138 of the multi-branched conduit after the third assembly 134 perforates the coronary artery 26. Inserting the first input end 124 of the multi-branched conduit into the myocardium access port 122 and the second input end 138 of the multi-branched conduit into proximal artery access port 136 creates and maintains two channels 140 and 142 from two different blood sources, namely the left ventricle 20 and the coronary artery 26 proximal to the blockage 28, into the output end 132 of the multi-branched conduit and into the coronary artery distal to the blockage 28.

Preferably, a multi-branch, valved conduit 126 is used having at least two branches 140 and 142 with valving means 144 located in branch 140. With access afforded by this surgical approach, the two input ends 124 and 138 and output end 132 of the valved conduit each can be inserted similar to the previous description of Figs. 6 and 7 without the assistance of remote guidance which avoids using a guide wire or the like through the interior of the conduit.

In an alternate embodiment of this surgical approach, each branch 140 and 142 of the conduit can initially be a separate component which can be connected together after the two input ends and output end have been inserted into the myocardium and the coronary artery proximal and distal to the blockage. The valving means 144 minimizing blood flow into the left ventricle is located in the branch 140 leading from the myocardium 16 between the first input end 124 and the connection to the second input end 138 and the output end 132. Alternately, the valving means 144 can be located near

the distal artery port 130 as shown in phantom as 148. Optionally, a second valving means 146 for minimizing blood flow into the proximal coronary artery can be located in branch 142 leading from the proximal coronary artery between the second input end 138 and the connection between the first input end 124 and the output end 132. A second valving means 146 is particularly useful if there is a valving means located near the distal artery port 130.

It should be understood that portions of different approaches can be combined. For example, a portion of the surgical approach described in Fig. 8 can be used to connect the proximal and distal coronary artery 26 with a channel like branch 142 external to the heart. Instead of providing another external channel like branch 140 to connect the left ventricle 20 with the distal coronary artery 26, a surgical approach as described in Figs. 1 or 4 can provide an internal channel 42 (Figs. 1 or 4) positioned through the myocardium 20. As a result, blood flow from the left ventricle 20 arrives to the distal coronary 26 by an internal channel 42 and from the proximal coronary artery through external channel like branch 142.

Fig. 9 illustrates another embodiment of a surgical approach which directly accesses and exposes the outside of the patient's heart and coronary vascular system 10 for the placement of a valved conduit 150 through an extended portion along, or at an obtuse angle through, the myocardium 16 rather than taking the shortest path roughly perpendicularly through the myocardium. Using a first needle/delivery assembly 154, proximal artery access port 156 is made on the exterior side 72 of the coronary artery. The assembly 154 is advanced through the interior 70 of the coronary artery and along the myocardium before eventually creating an access port 160 to the left ventricle 20 through the myocardium 16. The proximal artery access port 156 and left ventricle access port 160 are dilated to accommodate the delivery of one branch 162 of the valved conduit 150 so that the valved conduit 150 is positioned at least partially along the myocardium and is preferably subjected to the movement created by the rhythmic contractions of the beating heart.

Using a second needle/delivery assembly 166, a distal artery access port 168 is created through the coronary artery 26 at a point distal to the lesion or blockage 28 into the exterior side 18 of the myocardium to connect with or near the left ventricle access port 160. The second assembly 166 can immediately dilate the distal artery access port 168 and insert the other branch 164 of the valved conduit into the coronary artery 26. As

a result, the valved conduit 150 has two branches 162, 164 which traverse the myocardium 16 at an obtuse angle. The valved conduit 150 exhibits a substantially greater length compared to perpendicularly traversing the myocardium between the left ventricle 20 and coronary artery 26.

Although the valved conduit 150 can have a solid, rigid design, it is preferred in this embodiment to advantageously use the movement created by the rhythmic contractions of the beating heart to provide the regulation of the blood flow from the left ventricle 20 to the coronary artery 26 distal to the blockage 28. Accordingly, it is preferred that a substantial length the valved conduit 150 be made of a flexible material which allows the walls 152 of the valved conduit to flex with the rhythmic contractions of the beating heart and assist in the regulation of blood flow. The flexing of the conduit walls 152 can occur in several ways such as compression of its diameter or the lateral collapse of the conduit walls 152 upon themselves. It may be desirable to provide rigidity to the conduit walls 152 in the area of the valve 158 located near the access port 160 to preserve the integrity of the blood flow regulation by the conduit. It should be noted that the branches do not have to be connected and terminate at one access port 160. A second access port to the left ventricle is also suitable, so that each branch 162, 164 has a separate access port to the left ventricle 20.

Alternately, it is suitable to remove the valve 158 as a distinct component of the conduit by allowing the conduit walls 152 to flex by collapsing opposing walls against each other to provide the appropriate degree of closure during systole. It may also be desirable to provide for regulating blood through both branches by locating the valve 158 only in branch 162. Examples of the proper alignment of the valved conduit 150 traversing the myocardium 16 are described in more detail below.

Other means of positioning the valved conduit 150 along a more extensive path between the left ventricle 20 and coronary artery 26 are suitable for use in the present invention. For example and not limitation, the direct access to the exterior of the heart 10 allows a trough to be excised between the left ventricle access port 160 and the distal artery access port 168. The left ventricle access port 160 can be created at one end of the trough and the distal artery access port 168 at the other end of the trough. One end of the valved conduit 150 is then positioned into the left ventricle and extends within the trough to the other end of the valved conduit which is inserted into coronary artery 26 as previously described therein.

Although the position of the valved conduit 150 is specifically illustrated as traversing the myocardium along an extended path or obtuse angle, it should be noted that the present invention is not so limited. The valved conduit 150 can be positioned partially or wholly within the myocardium including other tissue layers enveloping the heart i.e. pericardium, epicardium, endocardium, etc., or external to the heart and vascular system, or in a combination thereof.

Another embodiment of the surgical approach using the valved conduit at least partially positioned within the myocardium is to utilize a valved conduit with only one branch similar to the methods illustrated in Figs. 1, 4 and 6. Optionally, other branches are added to the valved conduit 150 of Fig. 9 to connect to other sources of oxygenated blood, namely another coronary artery, or to deliver the oxygenated blood to multiple ischemic areas. Each additional branch can be positioned across the myocardium along an extended path or obtuse angle as described above or in a perpendicular direction across the myocardium.

Fig. 10 illustrates another embodiment of a surgical approach which directly accesses and exposes the outside of the patient's heart and coronary vascular system 10 for the placement of a valved conduit 180 across the myocardium 16. A needle/delivery assembly 182 creates an initial access port 184 in the exterior side 72 of the coronary artery distal to the blockage 28. The assembly 182 is advanced through the interior 70 of the coronary artery to create an access port 190 through the vascular wall 186 of an adjacent coronary vein 188. The assembly 182 is then advanced through the coronary vein 188 to create an access port 192 in the exterior side 18 of the myocardium and completely through the myocardium 16 into the left ventricle 20. The valved conduit 180 is then inserted into and through the myocardium 16 creating a channel 42 directly from the left ventricle 20 to the coronary vein 188. The blood flow into the coronary vein 188 is limited to a particular area or section 170 by inserting plugs 194 within the coronary vein proximal and distal to the access ports 190, 192. The plugs 194 can be moved into their respective positions by insertion through the access ports 184, 190. Another technique for inserting the plugs 194 is to perforate, dilate, and insert the plugs 194 directly through the exterior side of the coronary vein 188 near the area the plugs 194 are desired. Devices or techniques other than plugs 194 can be used to isolate a section of the coronary vein 188 such as by using a suture around the vein in a position at least proximal to the access ports 190, 192 to close off blood flow to the section.

A second conduit 196 is inserted into the access port 190 to maintain a second channel 198 between the coronary artery 26 and the coronary vein 188. As a result, blood flows during systole from the left ventricle 20 into the coronary vein 188 and subsequently into the coronary artery 26 distal to the blockage 28. The coronary vein 188 can provide a temporary reservoir of blood. The valved conduit 180 minimizes backflow of blood from the coronary vein and artery during diastole. Upon withdrawal of the assembly 182, the initial access port 184 is closed.

As illustrated, the conduit 180 can optionally include a reservoir connected to it for temporarily storing blood. The reservoir may be a separate container like the section 170 of the coronary vein 188 that is connected to the conduit 180 or a container that is integrally formed with the surface of the conduit. The reservoir can also be effectively formed from a material which has the ability to expand and contract so that it becomes a reservoir during certain periods of the heart cycle.

The assembly 182 can be elongated to initially contain both the valved conduit 180 and the second conduit 196 so that each may be respectively positioned without withdrawing the needle assembly from the initial access port 184. Other alternates are available, such as withdrawing the needle assembly 182 to reload with the conduit not first placed in position. Or, temporarily dilating the access port 184 with another device so that a second needle/delivery assembly can be inserted through the same access port.

Although there is only one valved conduit 180 and it is positioned completely through the myocardium 16, the present invention includes several other options for regulating blood flow. For example, one option is to position the valved conduit 180 between the coronary artery 26 and coronary vein 188 and position the second conduit 196 without a valve through the myocardium between the left ventricle 20 and the coronary vein 188. This arrangement creates a reservoir of blood within the coronary vein 188 which may allow for blood flow into the coronary artery 26 during diastole.

Another option positions the valved conduit 180 and second conduit 196 as illustrated in Fig. 10. However, a valve shown in phantom as 180A is added to the second conduit 196. As a result, the coronary vein 188 provides a reservoir of blood in section 170 which augments blood flow into the coronary artery 26 during diastole.

Another embodiment of this surgical approach wherein the channel between the left ventricle and coronary artery is transvascular and transmyocardial is illustrated in Fig. 11. An initial access port 184A is created in the top exterior of the coronary vein 188

instead of the coronary artery 26. The assembly 182 is advanced to create the access port 190 into the coronary artery 26, to insert the second conduit 196 and is then withdrawn. The assembly is also advanced from the initial access port 184A to create the access port 192 into the myocardium 16, insert the valved conduit 180 and is then withdrawn.

Alternately, the initial access port 184A is created to advance the assembly 182 and create an access port from the coronary vein 188 to either the left ventricle 20 through the myocardium 16 or to the coronary artery 26, but not both. Another initial access port 184B is created with the same or another assembly to complete the remaining access port. For example, access port 192 is made through the myocardium and the alternate access port 184B is used to make alternative access port 190B into the coronary artery 26. As a result, the alignment of the access ports 190B, 192 is offset from one another.

Although a valved conduit 180 is specifically illustrated in Figs. 10 and 11, the coronary vein 188 itself can be used to regulate the flow of blood from the left ventricle 20 into the coronary artery 26. In this embodiment, the conduits 180 and 196 need not be valved, but simply maintain the respective channels. As discussed in more detail below, the natural valving function of vascular tissue in the isolated section of the coronary vein 188 can be advantageously used to regulate the flow of blood.

The present invention includes still another surgical approach wherein transvascular and transmyocardial channels between the left ventricle and coronary artery extend to more than one blood source as illustrated in Fig. 12. An additional initial access port 174A is created in the top exterior of the coronary vein 188 at a position which is proximal to the blockage 28 in the adjacent coronary artery 26. The assembly 182 is advanced through the interior of the coronary vein 188 to create an additional access port 172 for a third channel 178 through the exterior wall 72 of an adjacent coronary artery. A third conduit 176 is inserted into the additional second access port 172 to maintain the channel 178. One of the plugs 194 is inserted into the coronary vein 188 in a proximal position to the additional initial access port 174A.

Alternately, the additional initial access port 174B is created in the top exterior of the coronary artery proximal to the blockage 28. The assembly 182 is then advanced through the interior of the coronary artery to create the third channel 178 through the exterior wall 186 of an adjacent coronary vein.

Another method of the present invention is a surgical approach which directly accesses and exposes the outside of the patient's heart and coronary vascular system 10

through the chest area as illustrated in Fig. 13. As described herein, a needle delivery assembly can be used to perforate and dilate an access port 200 in the exterior side 18 of the myocardium so as to insert a valved conduit 204, preferably having a horizontal branch 208 to form a T-shape, into the left ventricle 20. The valved conduit 204 is positioned so that the branch 208 lies within the myocardium and the end 210 of the valved conduit extends within the left ventricle 20. The branch 208 is positioned to lie parallel to the myocardium 16. The valve 212 in the conduit is preferably positioned near the end 210. After insertion of the valved conduit 204, the exterior side 18 of the myocardium is closed by suturing or other suitable closure means.

Alternately, an incision can be made along a suitable course in the exterior side 18 of the myocardium such as along the phrenic nerve into the vascular area of myocardium 16 above the left ventricle 20 in front of the coronary artery. The incision is deepened almost to the interior side 24 of the myocardium or the endocardium 202. Optionally, a small cavity 206 can be created to assist in the placement of the conduit 204. As previously described, a needle assembly is then used to perforate through the endocardium 202 or remaining myocardium below the incision 200, to the left ventricle 20.

An example of suitable dimensions for the preferred T-shaped valved conduit 204 is about a 4 mm diameter with a vertical branch 214 of about 15 mm and the horizontal branch 208 of about 20 mm long. The horizontal branch 208 is provided to divert blood flow into a direction parallel to the myocardium 16 layer. Other designs for the valved conduit 204 are suitable for use in the present invention. For example and not limitation, the valved conduit 204 can be a straight stem or have a two horizontal branches in a cross shape. The valved conduit 204 can be made of a porous material that allows blood flow to emanate from the entire length, or selected portions, of the vertical branch 214 and/or horizontal branch 208.

Another preferred method of the present invention is a percutaneous approach which generally introduces a catheter or other guidance/delivery device into the blood source such as the left ventricle. A catheter 220 is placed into the circulatory system 10 at a remote access site such as the femoral artery and advanced through the aortic valve into the left ventricle 20 as illustrated in Fig. 14. The catheter 220 then is directed to the interior side 24 of the myocardium 16 underneath the coronary artery 26 where a penetrating or perforating needle 222 is delivered and advanced from the left ventricle 20

through the myocardium 16 into the coronary artery 26 to create an access port 224 therethrough.

Once the catheter 220 has been guided to the desired location, the perforating needle 222 is exchanged for a valved conduit 226 which is delivered to the access port 224 and inserted into the myocardium 16. As described above, the valved conduit 226 extends completely through the myocardium 16 to create and maintain a channel 42 between the left vertical 20 and the coronary artery 26 distal to the blockage 28.

There are several conventional techniques for locating the position of a catheter 220 in various places in the human body. For example and not limitation, the locating means can be an ultrasound system, magnetic resonance imaging, computer aided tomography or an echocardiograph. A fluid or medium such as a dye can be introduced by conventional means into the left ventricle 20 that allows its identification by a scanning instrument and provides a background to identify the location of the guided catheter 220 in relation to the coronary artery 26 and the left ventricle 20.

A suitable inventive method using the percutaneous approach is illustrated in Figs. 15 and 16. A catheter 228 and guide wire 238 are inserted into the coronary artery 26 from a remote access site such as along the femoral artery. The guide wire 238 is used to cross the blockage 28 and then the catheter 228 is inserted over the guide wire and advanced past the blockage. The catheter 228 includes a body 230 having a distal end 232 and proximal end 234 with a window 236. A guide wire 238 assists in guiding the catheter 228 into the desired position and exchanging a perforating needle 244 and a valved conduit as discussed above. The window 236 is rotated for proper orientation so that the window 236 faces the tissue layer of the coronary artery 26 against the exterior side 18 of the myocardium wherein an access port 248 is to be created. Optionally, the body 230 includes a balloon 240 which can retractably expand against the inner tissue wall of the coronary artery 26 to hold the window 236 in its proper orientation.

The body 230 includes a ramp 242 which directs the perforating needle 244 on a wire into the tissue layer to create the access port 248. Preferably, the needle 244 has a bore in its center to provide for back bleeding as means of evidencing the position of the needle 244. Alternately, the scanning instrument can determine the position of the needle 244 advancement. Subsequently, the ramp 242 directs the insertion of the valved conduit 250 into the created access port.

(c) wherein the opening in the wall of the coronary artery is spaced from the opening in the tissue along a longitudinal axis of the coronary artery so that blood flows into the coronary artery lumen at an area located away from the opening in the wall of the coronary artery.

24. The method of claim 23, wherein steps (a) and (b) are carried out by perforating and dilating the outer wall of the coronary artery and tissue surrounding the blood source to create the openings therein.

25. The method of claim 23, wherein steps (a), (b) and (c) are carried out by passing a device through the wall of the coronary artery into the lumen of the artery, moving the device within the lumen along the longitudinal axis of the artery, and passing the device through the tissue to communicate the coronary artery lumen with the blood source.

26. The method of claim 23, wherein steps (a), (b) and (c) are carried out while exposing at least a portion of the patient's heart for surgical access

27. The method of claim 23, wherein step (c) is carried out by entering the lumen of the coronary artery and removing tissue from the wall of the artery to form the opening that communicates with the source of oxygenated blood.

28. The method of claim 27, wherein the blood source is the left ventricle and the tissue is removed from the myocardium.

29. The method of claim 23, further comprising accessing the lumen of the coronary artery to carry out step (b).

30. A method for increasing the flow of blood to a coronary artery, the method comprising the steps of:

(a) creating a channel in the myocardium of a patient's heart;

(b) placing the channel in communication with a coronary artery and a heart chamber containing blood; and

(c) orienting the channel in the myocardium so that movement of the myocardium causes the channel to be at least partially open during one phase of the heart cycle and at least partially closed during another phase of the heart cycle.

31. The method of claim 30, wherein the channel is formed by a bore passing through the myocardium that places the coronary artery in communication with the heart chamber, the bore being defined by tissue of the myocardium.

32. The method of claim 30, wherein the channel is formed by a conduit that is positioned in the myocardium and the conduit has a portion that collapses to at least partially close during diastole.

33. The method of claim 30, wherein the channel has a length and a diameter which vary to regulate blood flow as the myocardium moves during the two phases of the heart cycle.

34. The method of claim 30, wherein the channel is oriented in the myocardium so that at least a portion of the channel extends along a direction that is transverse to a line passing perpendicularly through the myocardium.

35. The method of claim 34, wherein the portion of the channel extends along a direction that is generally perpendicular to a line passing perpendicularly through the myocardium.

36. The method of claim 34, wherein the channel follows a curved path through the myocardium.

37. The method of claim 34, wherein the channel comprises two segments that extend along a first direction with respect to the myocardium and are connected by a segment that extends along a second direction with respect to the myocardium.

38. The method of claim 34, wherein the one phase of the heart cycle is systole and the other phase of the heart cycle is diastole.

39. A method for providing blood flow to a selected site in a patient's arterial vascular system, the method comprising steps of:

a) placing a first end of a conduit in flow communication with a heart chamber;

b) placing a second end of the conduit in flow communication with the selected site in the patient's arterial vascular system;

c) connecting the first and second ends of the conduit to establish a blood flow path between the heart chamber and the selected site in the arterial vascular system; and

d) maintaining the conduit in an open position for blood flow through at least one of the diastolic and systolic phases of the heart cycle.

40. The method of claim 39, further comprising regulating blood flow in the conduit to minimize blood flow from the arterial vascular system to the heart chamber during the diastolic phase of the heart cycle.

41. A system for placing a guide member through the wall of a patient's heart so that the guide member extends through a coronary artery into a heart chamber, the system comprising:

an introducer sized and configured for placement through a coronary artery and the wall of a patient's heart into a heart chamber; and

a guide member sized and configured to be positioned in the introducer and placed through the coronary artery and the heart wall into the heart chamber, the guide member having a proximal portion adapted to remain outside the heart and a distal portion adapted to be passed into and then back out of the heart chamber;

wherein the guide member is passed through the introducer and moves through the coronary artery and the heart wall to a location within the heart chamber.

42. The system of claim 41, wherein the guide member is a guide wire and the distal portion of the guide wire includes a distal end that is passed through the introducer.

43. The system of claim 41, wherein one of the introducer and the guide member is configured to direct the distal portion of the guide member to a predetermined location within the heart chamber upon introducing the guide member into the chamber.

44. The system of claim 43, wherein the introducer is a hollow needle with a curved portion configured to direct the distal portion of the guide member toward the wall of the heart.

45. A device for delivering a conduit into the wall of a patient's heart to form a blood flow path between a heart chamber and a patient's arterial vascular system, the device comprising:

a conduit having an exterior and an interior;

a sheath disposed over at least a portion of the exterior of the conduit, the sheath being movable to selectively expose the portion of the conduit covered by the sheath to tissue upon positioning the conduit at a desired location with respect to a patient's heart; and

a mechanism coupled to one of the conduit and the sheath for imparting relative movement to the conduit and sheath so as to expose the portion of the conduit to tissue once the conduit is located in said desired position.

46. The device of claim 45, wherein the mechanism is a rod disposed against an end of the conduit, the rod being movable to move the conduit from within the sheath to expose the conduit.

47. The device of claim 45, wherein the sheath is configured to be peeled apart and removed from the conduit.

48. A device for accessing a chamber of a patient's heart for use in forming a blood flow path between the heart chamber and the patient's arterial vascular system, the device comprising:

a shaft sized and configured to access a heart chamber by being passed through the heart wall, the shaft having a proximal end and distal end, the distal end of the shaft being adapted to enter the heart chamber; and

a flashback lumen extending over at least a portion of the length of the shaft and communicating with an opening disposed adjacent the distal end of the shaft, wherein an area of the shaft located adjacent the proximal end is configured to allow visual confirmation of the presence of blood in the flashback lumen;

wherein placing the distal end of the shaft in the heart chamber causes blood to enter the opening of the flashback lumen to provide visual confirmation that the distal end of the shaft is located in the heart chamber.

49. The device of claim 48, wherein the shaft has a plurality of openings that communicate with the flashback lumen.

50. The device of claim 48, wherein the shaft has a plurality of markings for indicating the position of the shaft relative to the tissue of the heart wall.

51. A device for use in forming a blood flow path between a source of oxygenated blood and a patient's coronary artery, the device comprising:

a conduit sized and configured to be positioned in tissue at a location that places a coronary artery in flow communication with a source of oxygenated blood;

wherein the conduit is provided with means for retaining the conduit in position by engaging the tissue so as to substantially fix the conduit in position.

52. A device for use in forming a blood flow path between a heart chamber and a patient's coronary artery, the device comprising:

a conduit sized and configured to be positioned in the myocardium at a location that places a coronary artery in flow communication with a heart chamber, the conduit having a length;

wherein the conduit is provided with means for varying the length of the conduit in response to variations in the thickness of the myocardium during the systolic and diastolic phases of the heart cycle.

53. The device of claim 52, wherein the conduit has a width and further comprising means for varying the width of the conduit in response to variations in the thickness of the myocardium during the systolic and diastolic phases of the heart cycle.

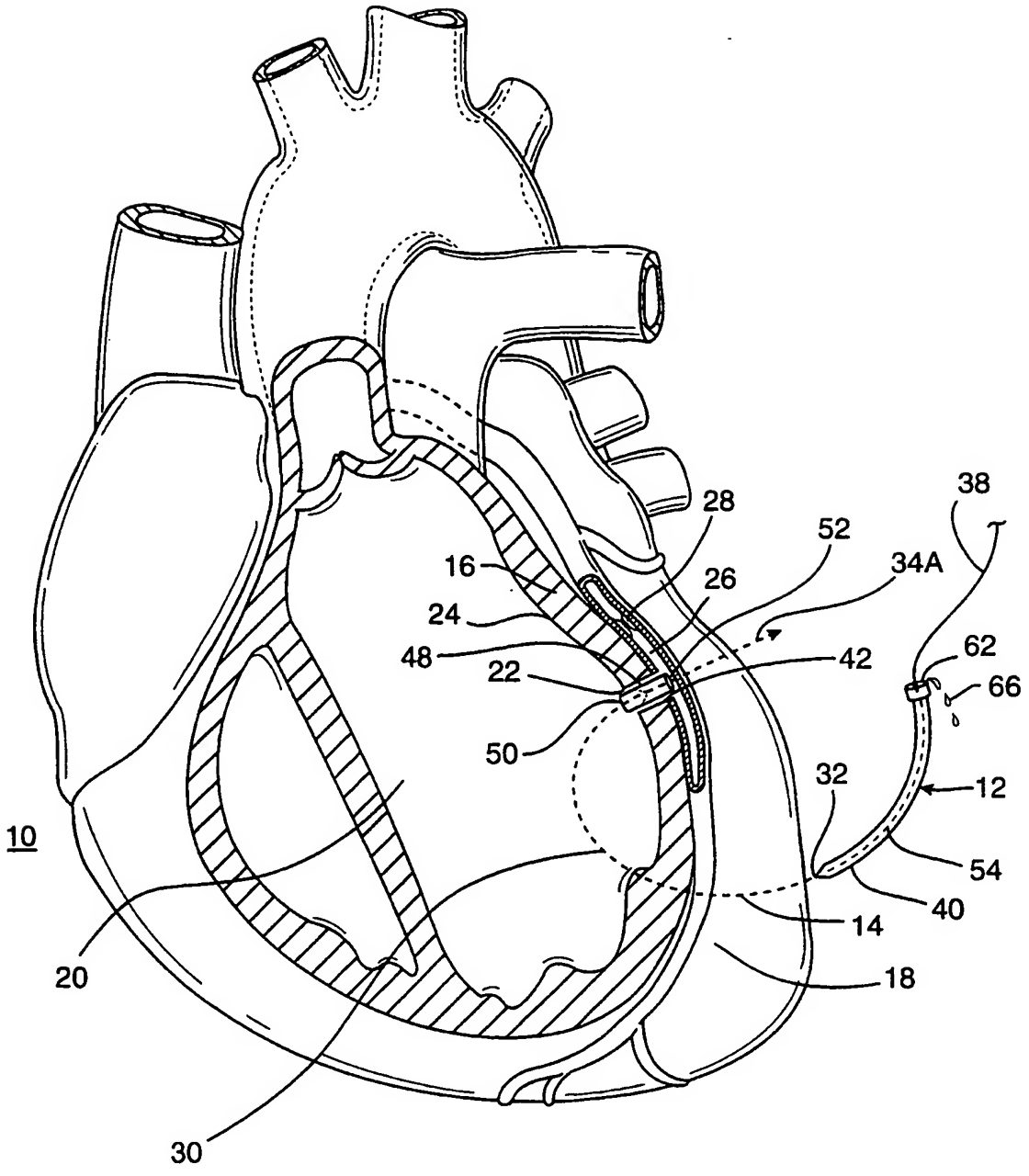

FIG. 1

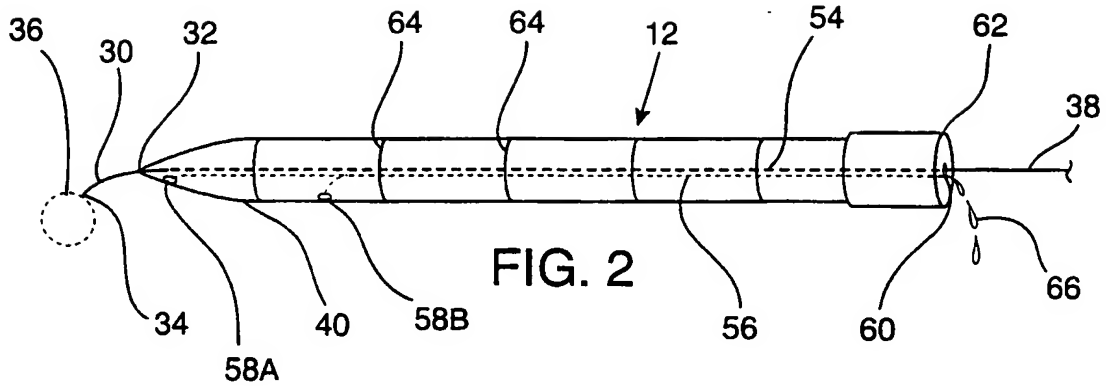

FIG. 2

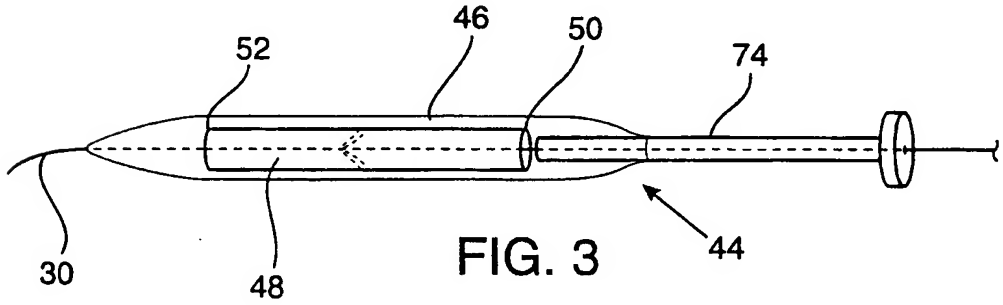

FIG. 3

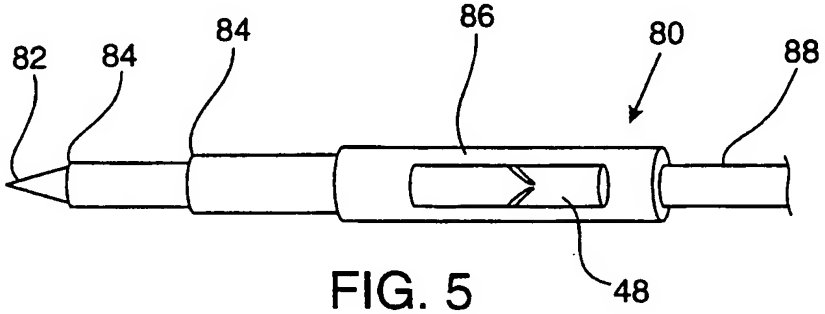

FIG. 5

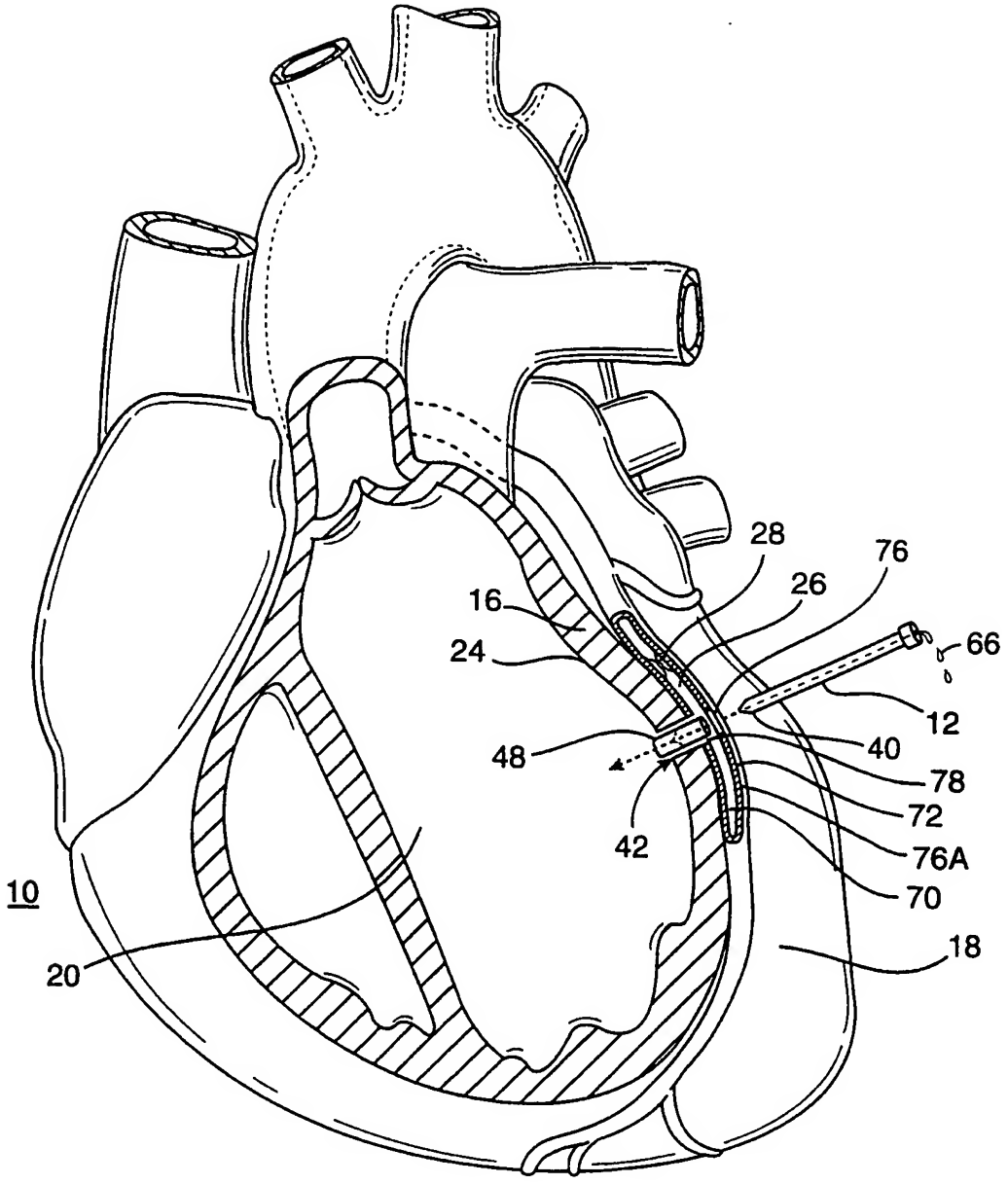

FIG. 4

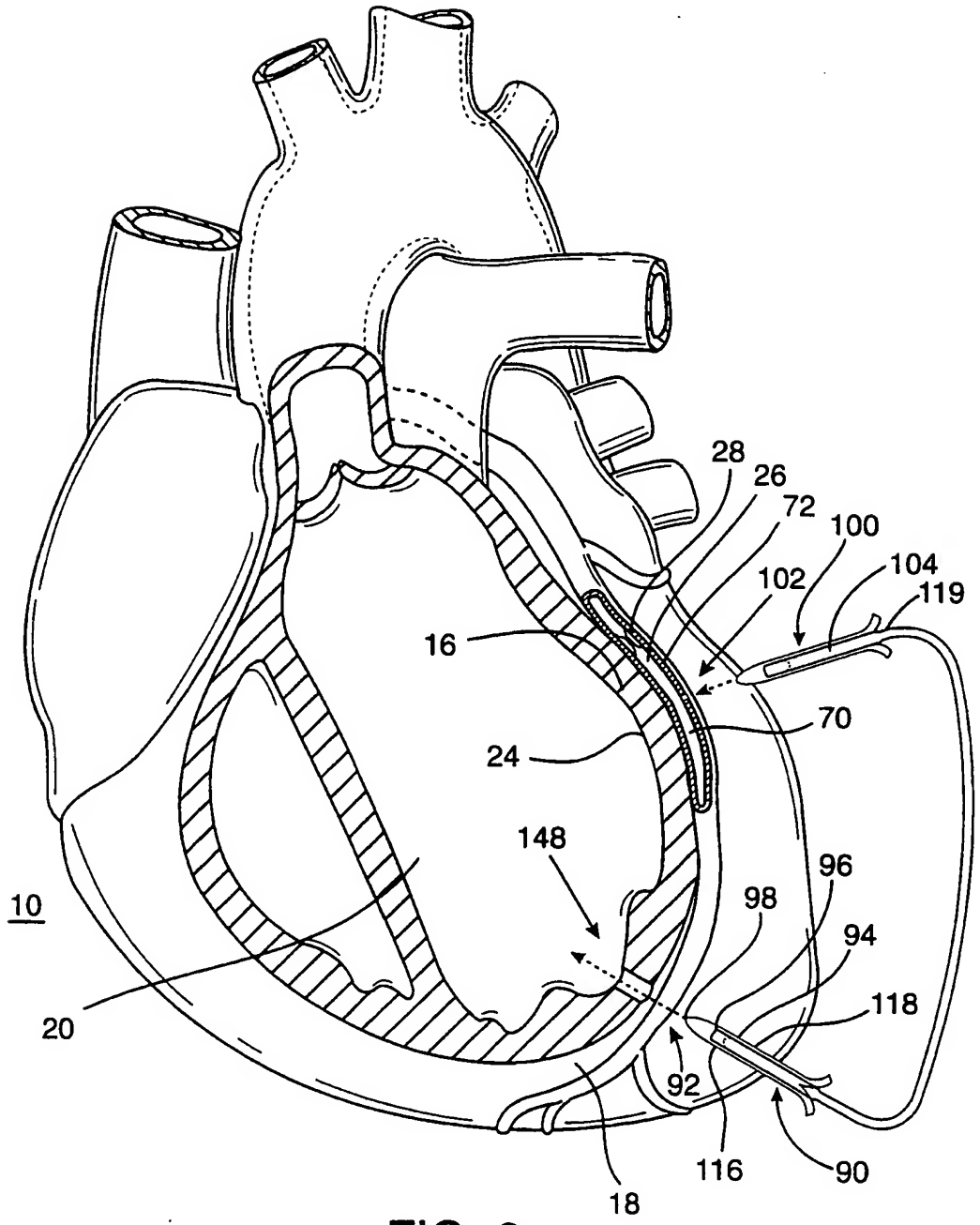

FIG. 6

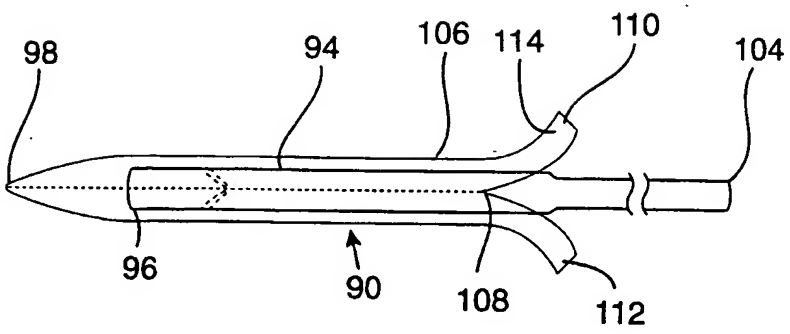
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FIG. 7

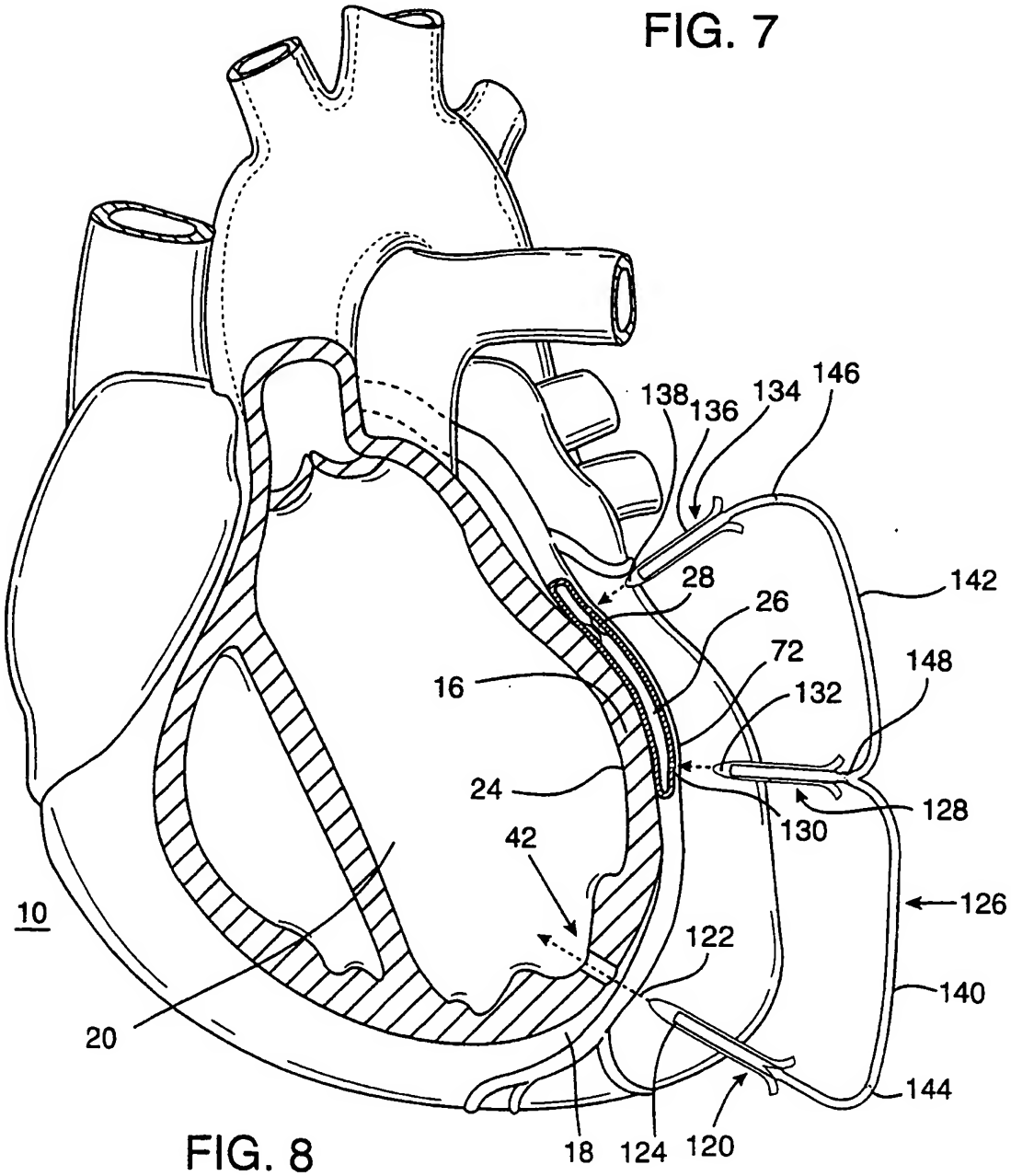
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FIG. 8

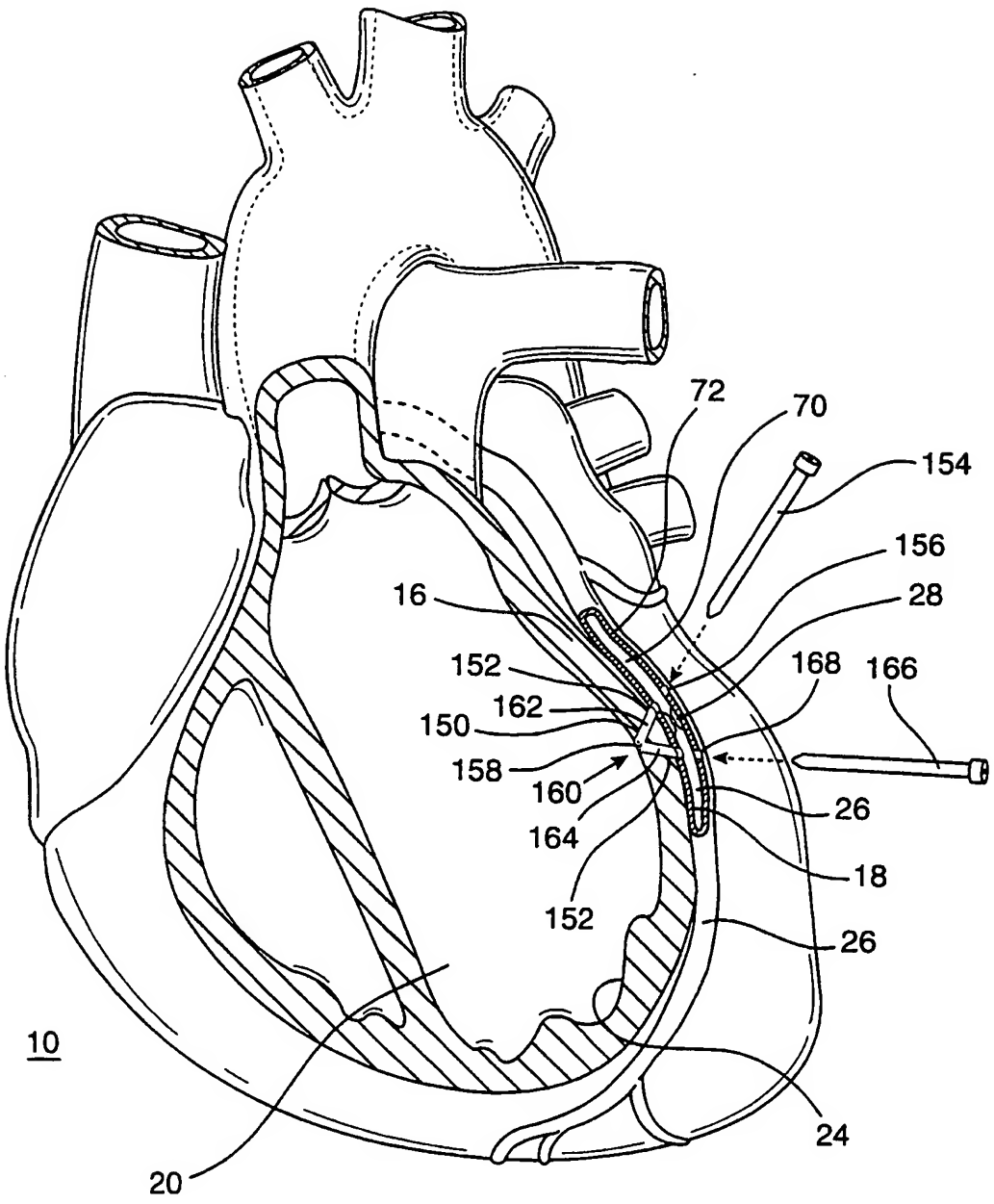
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FIG. 9

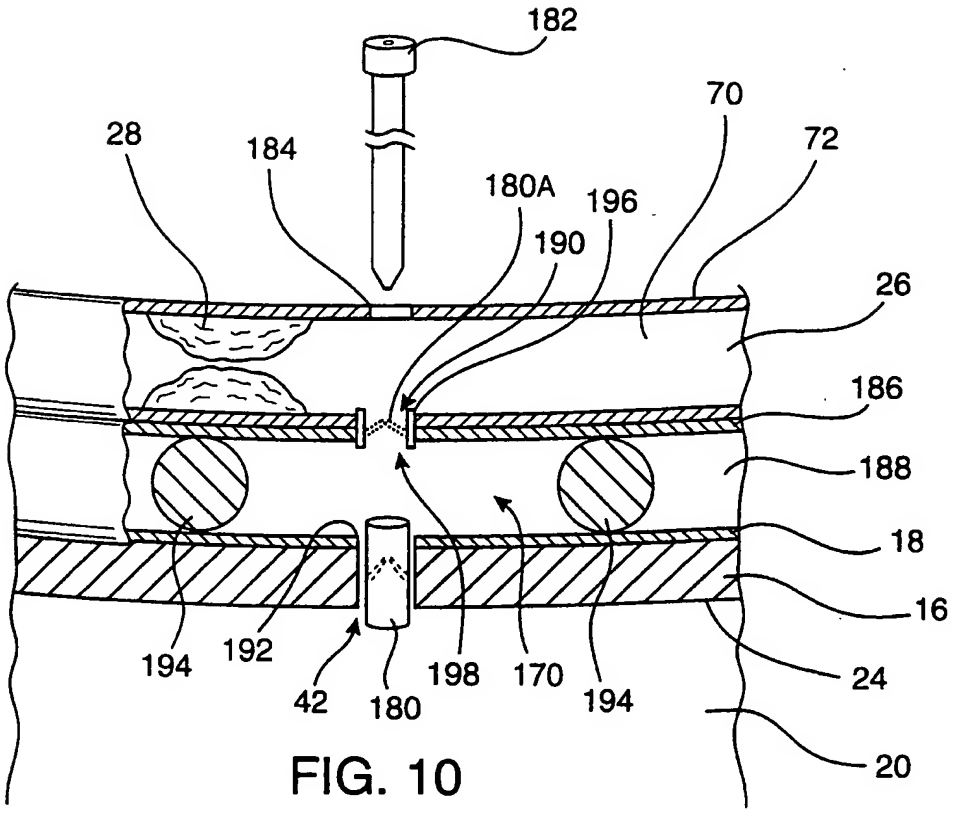
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FIG. 10

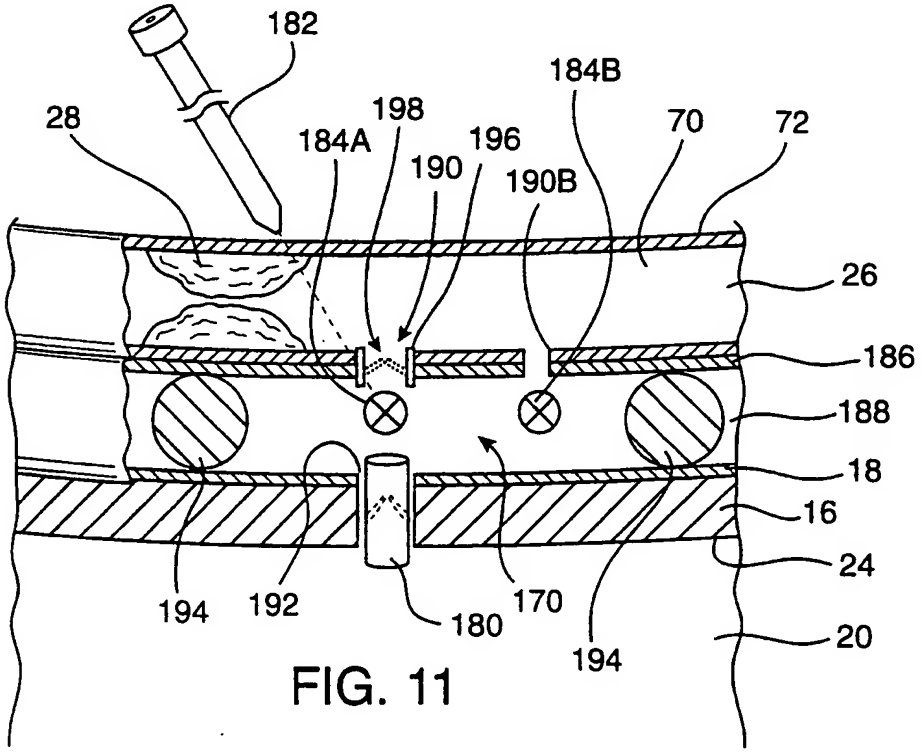
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FIG. 11

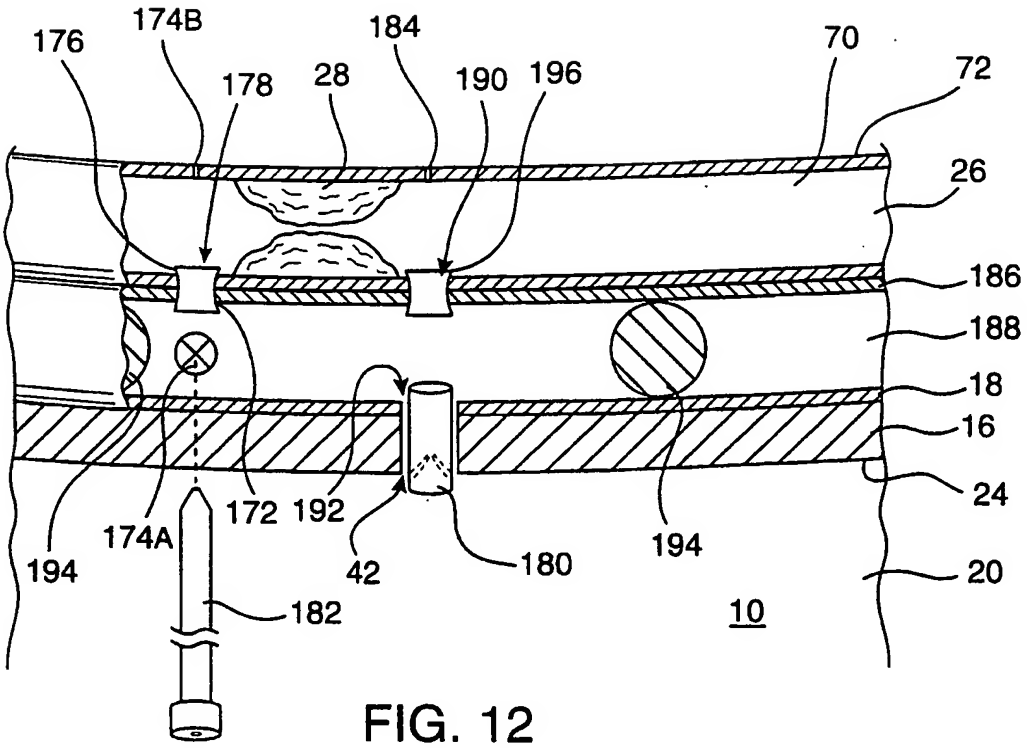
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FIG. 12

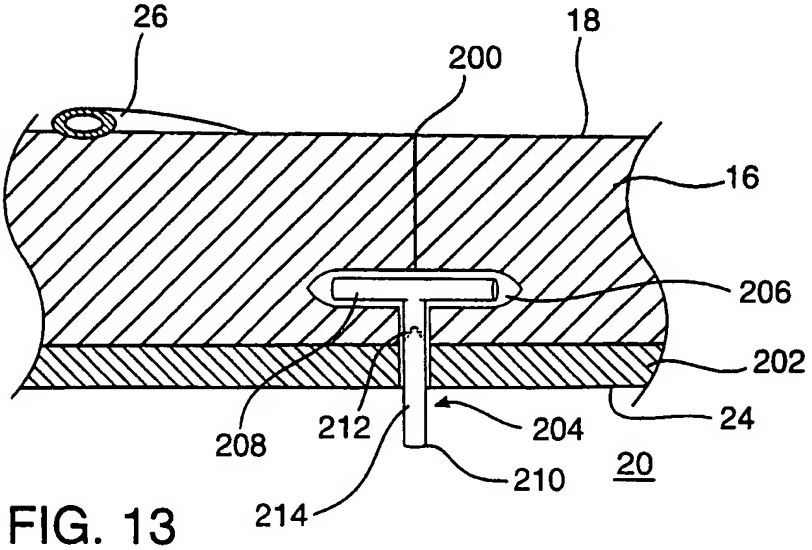
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FIG. 13

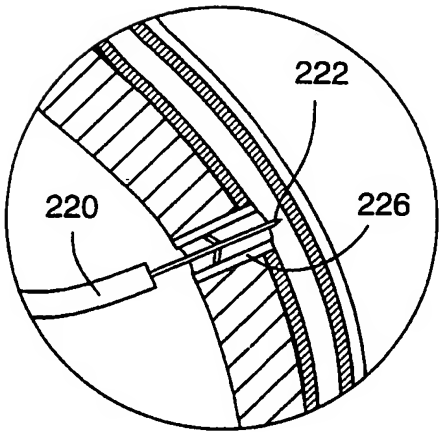

FIG. 14A

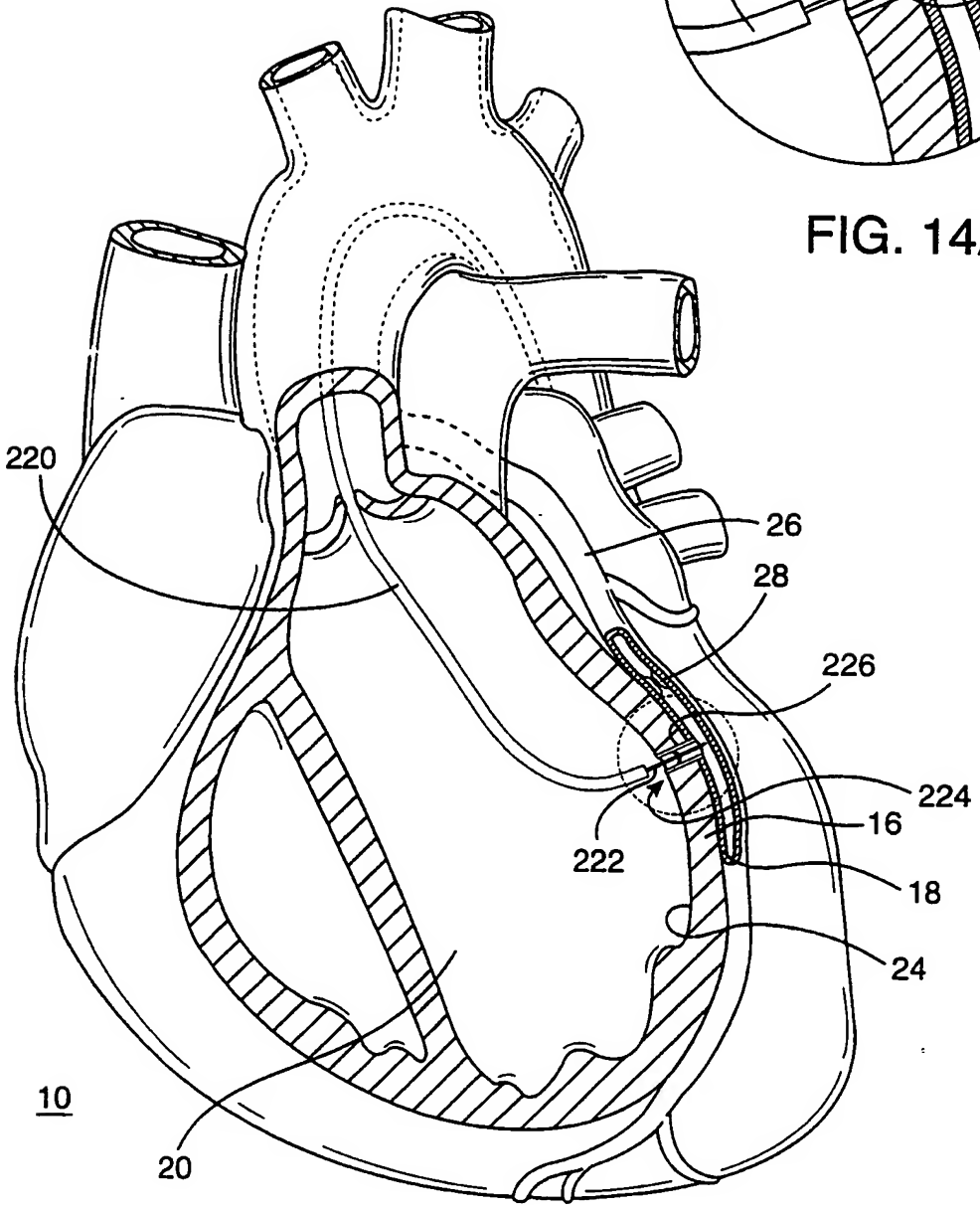

FIG. 14

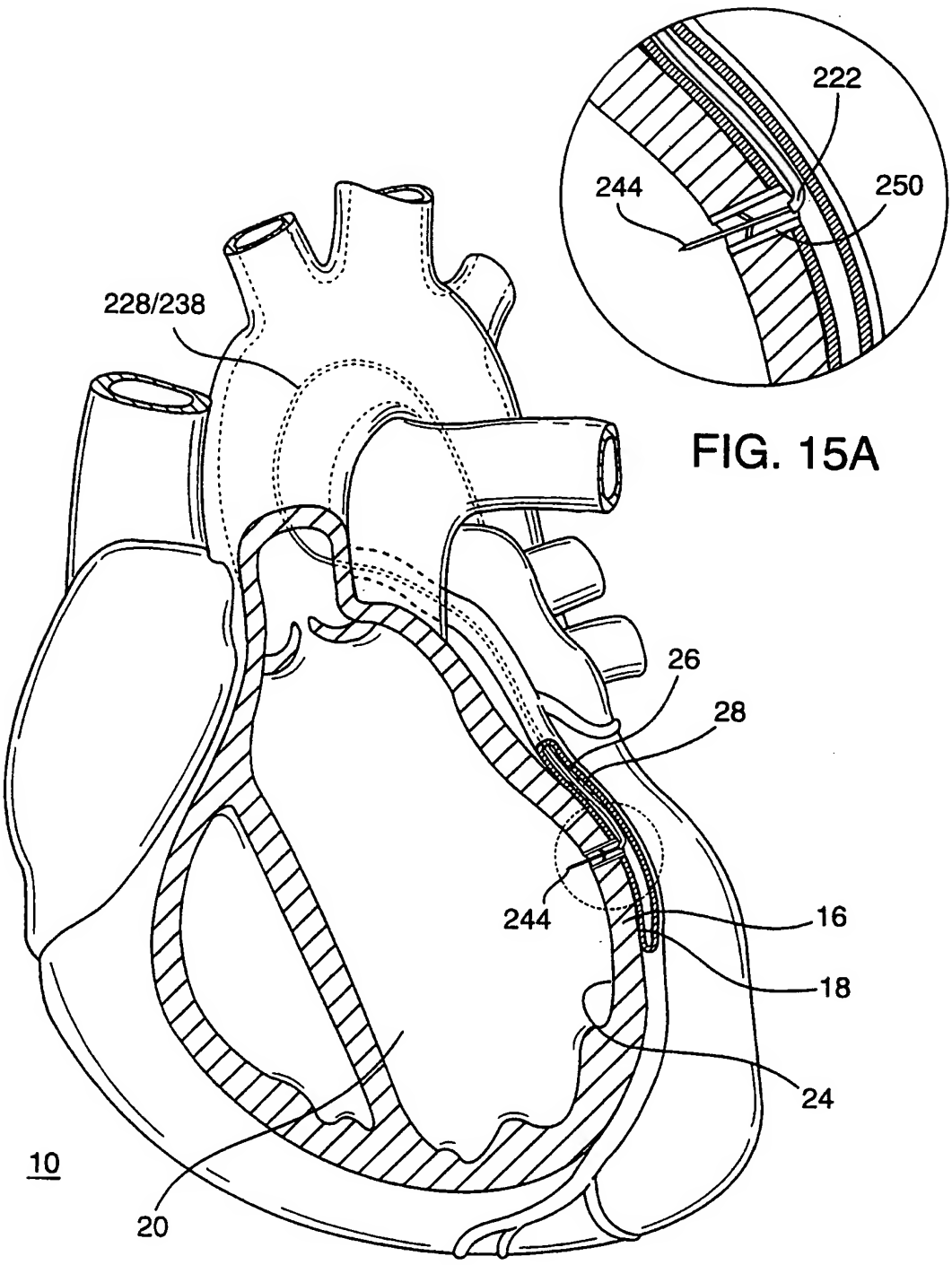

FIG. 15A

FIG. 15

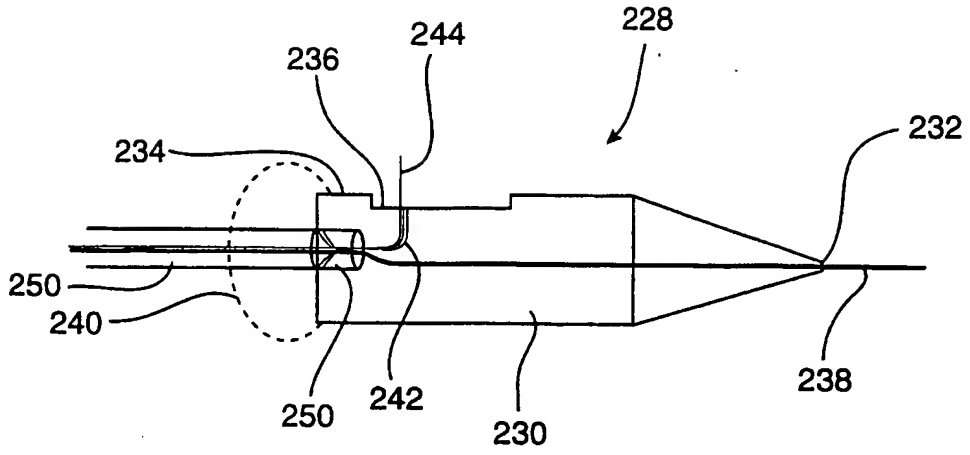
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FIG. 16

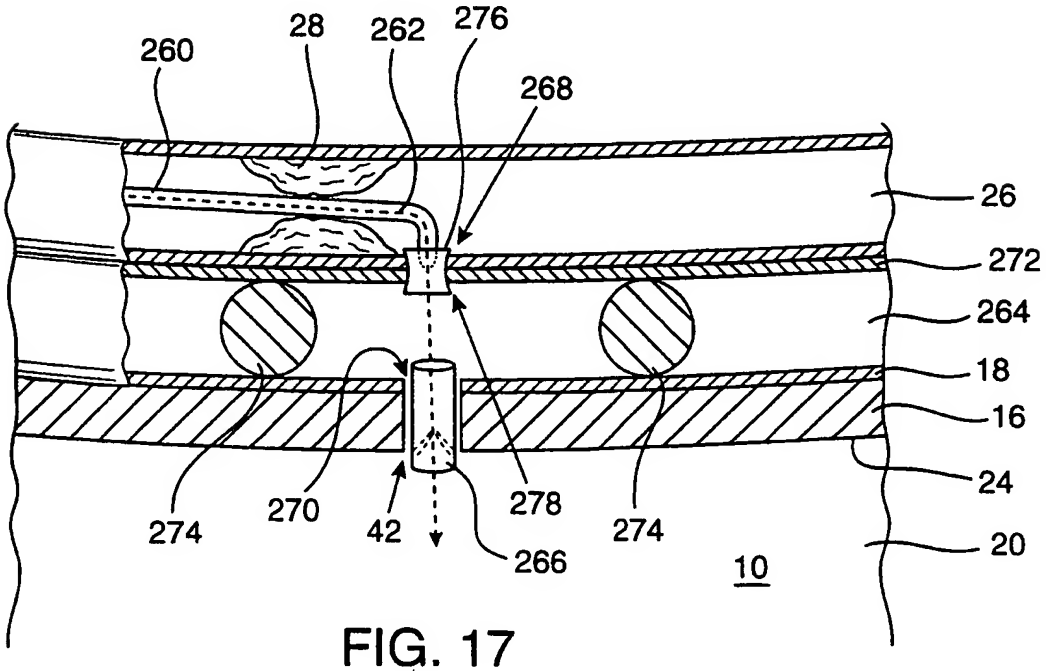
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FIG. 17

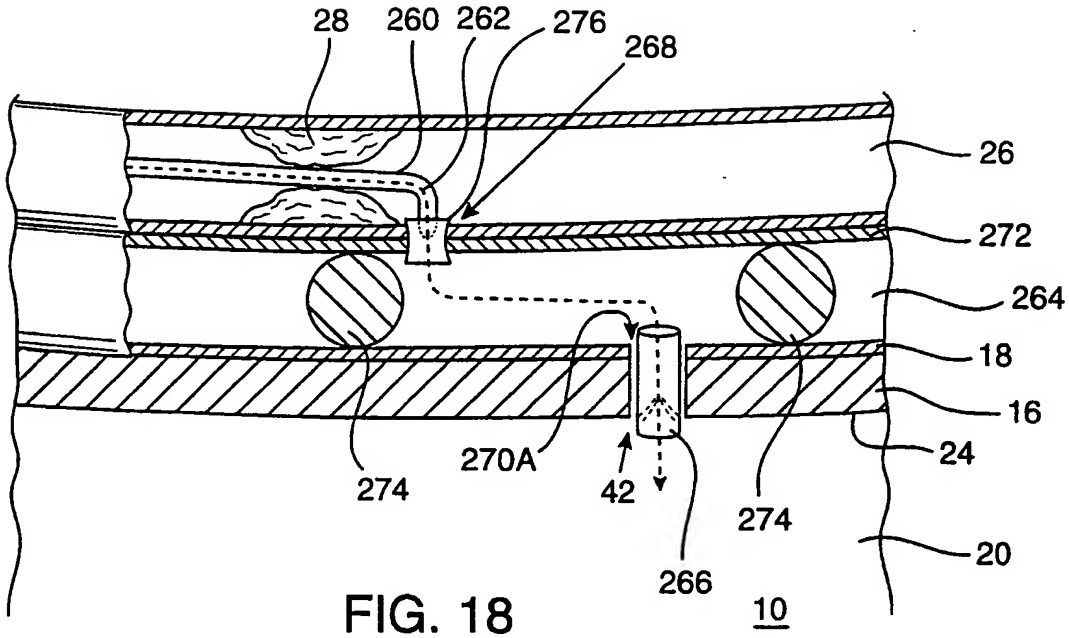
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FIG. 18

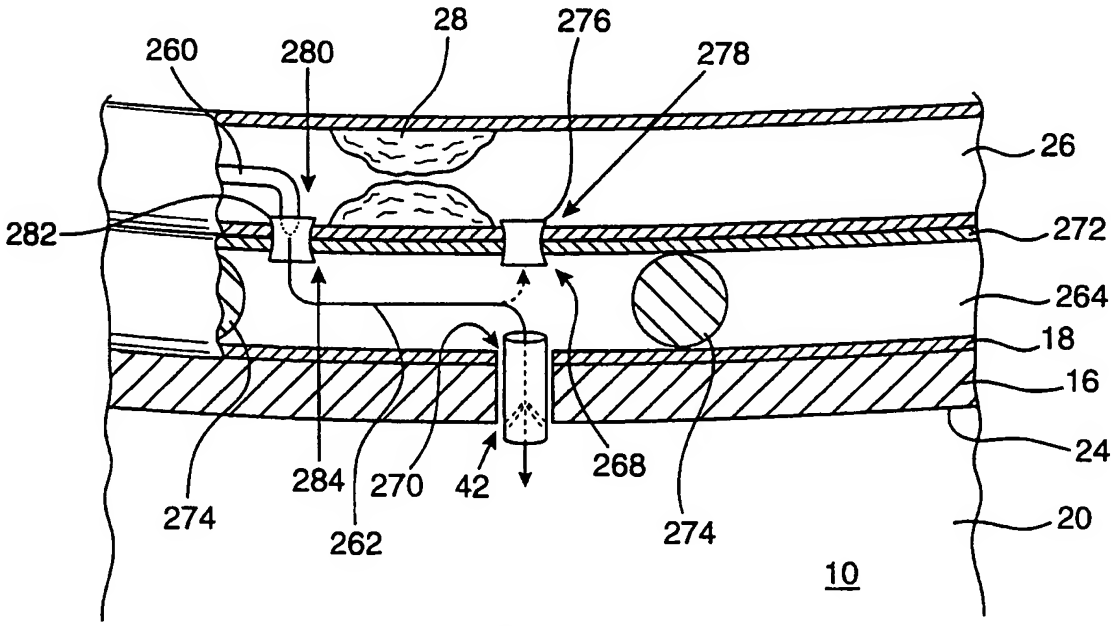
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FIG. 19

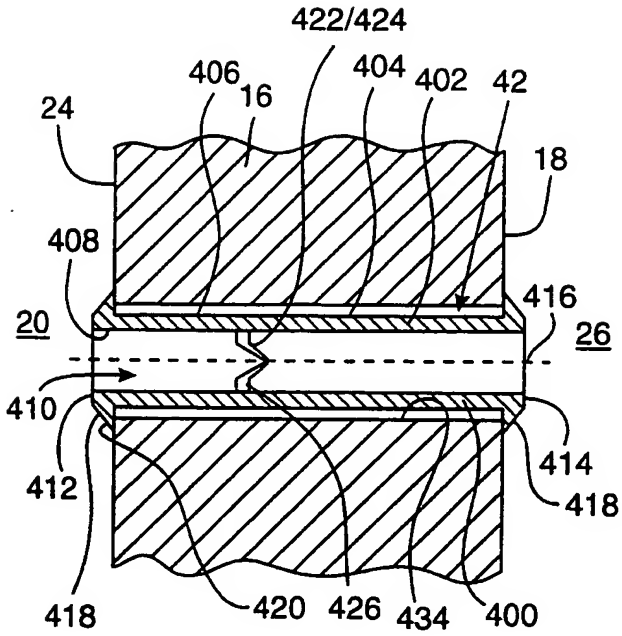

FIG. 20

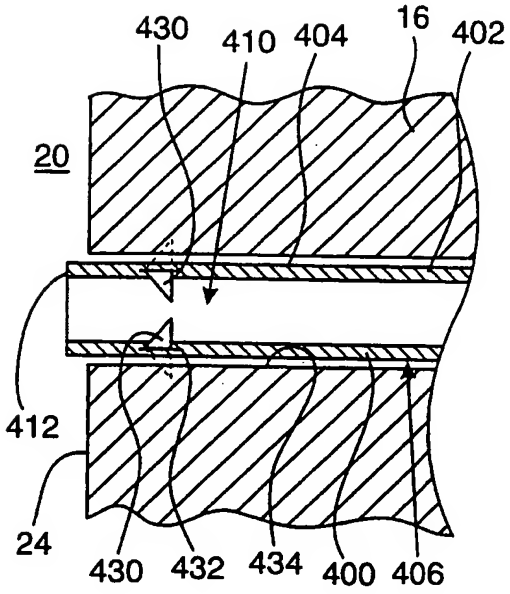

FIG. 21

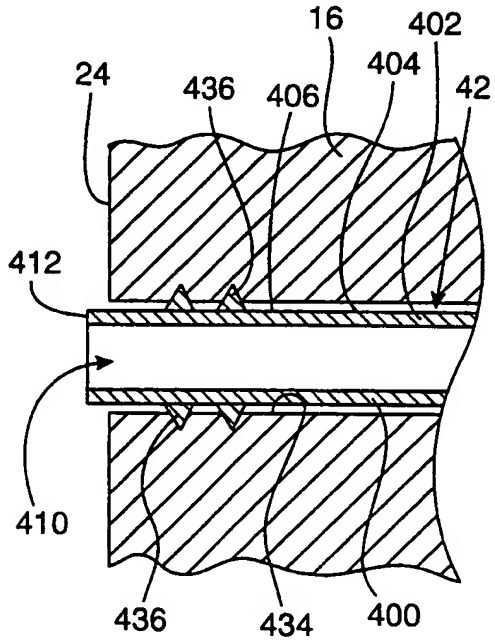

FIG. 22

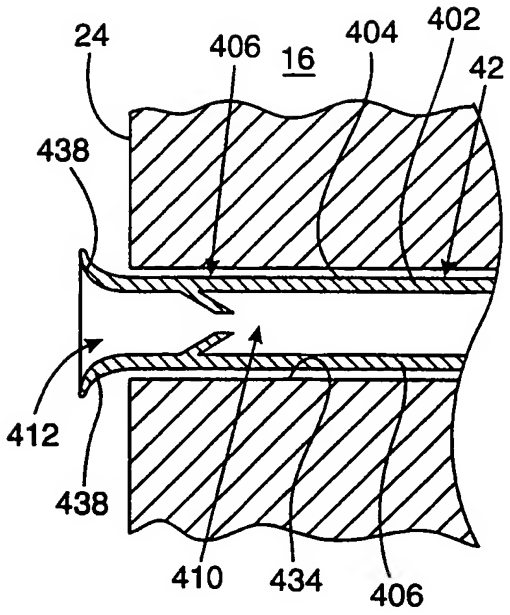

FIG. 23

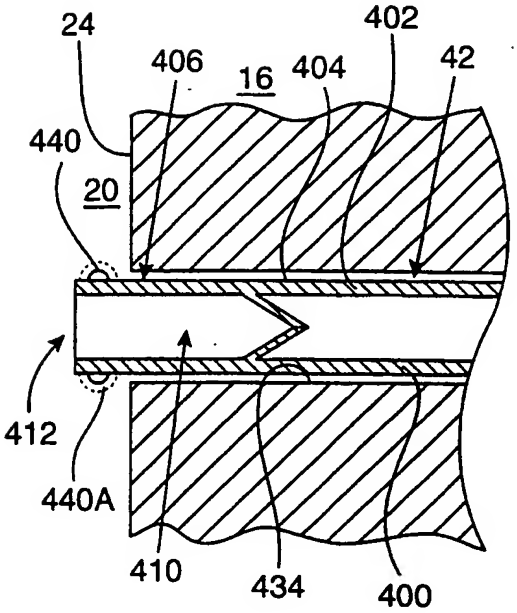

FIG. 24

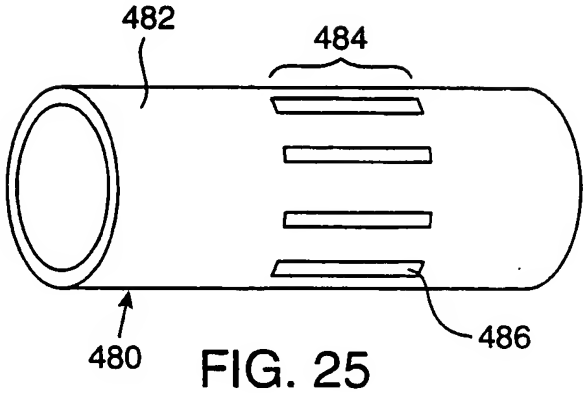

FIG. 25

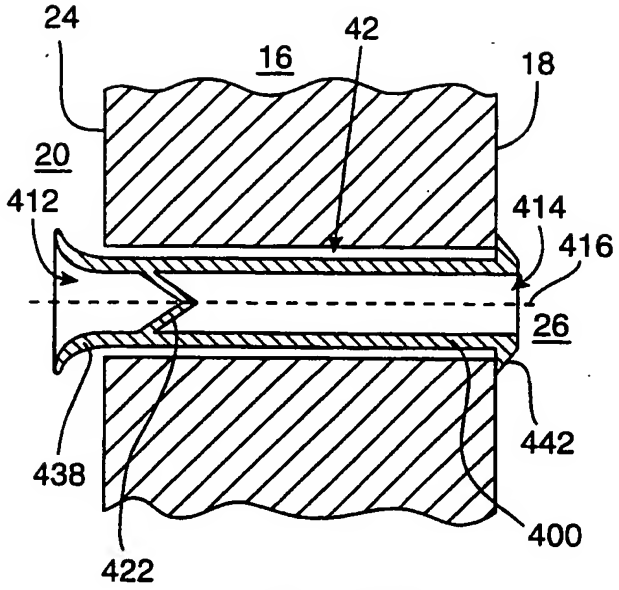

FIG. 26A

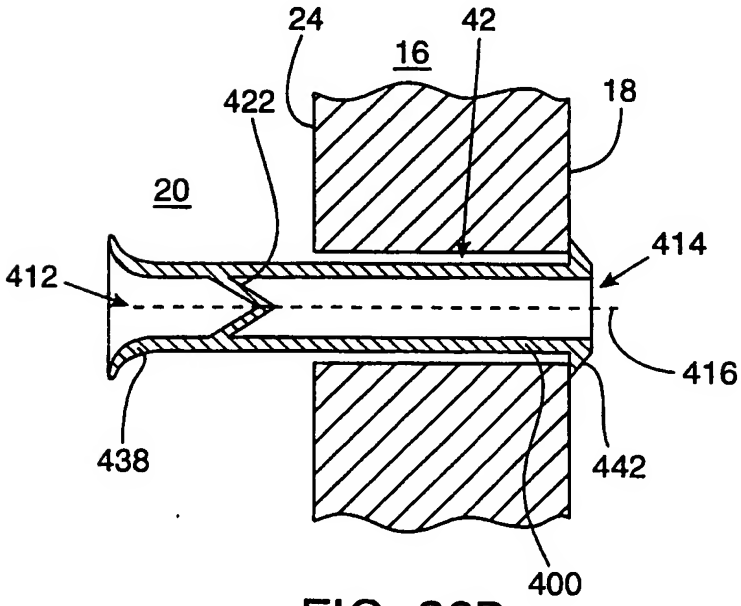

FIG. 26B

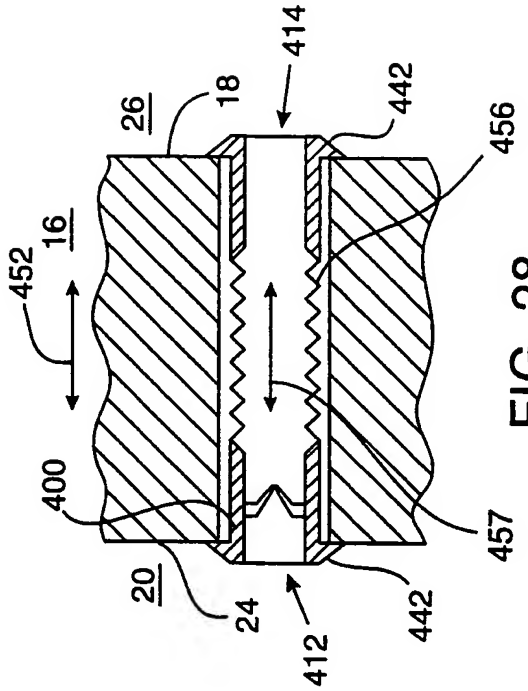

FIG. 28

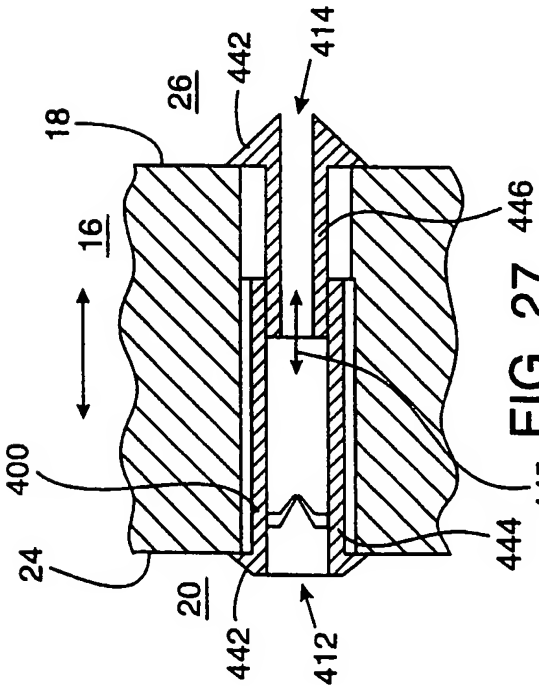

FIG. 27

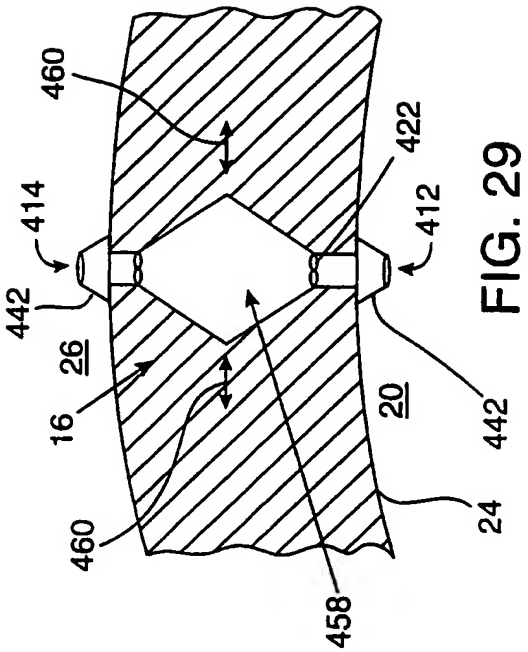

FIG. 29

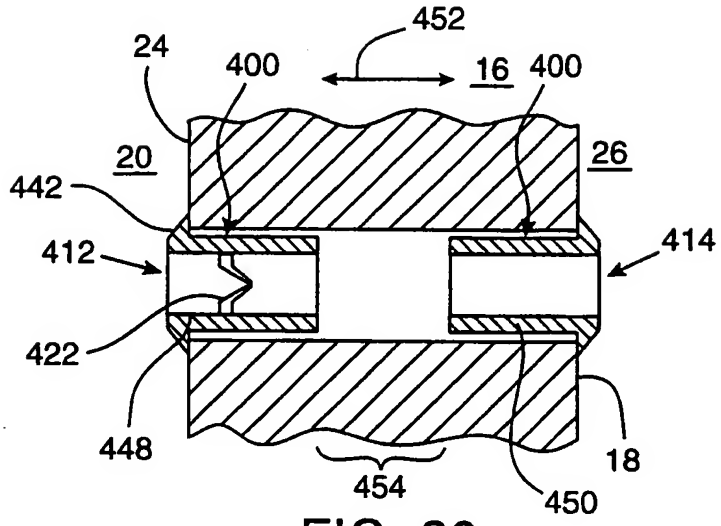
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FIG. 30

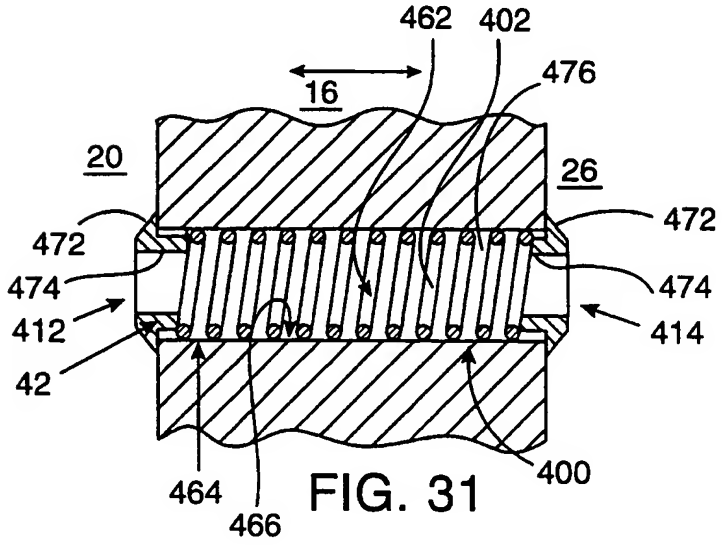
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FIG. 31

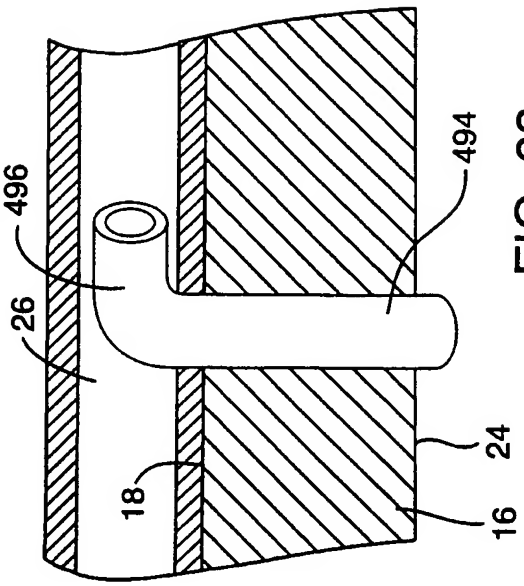

FIG. 33

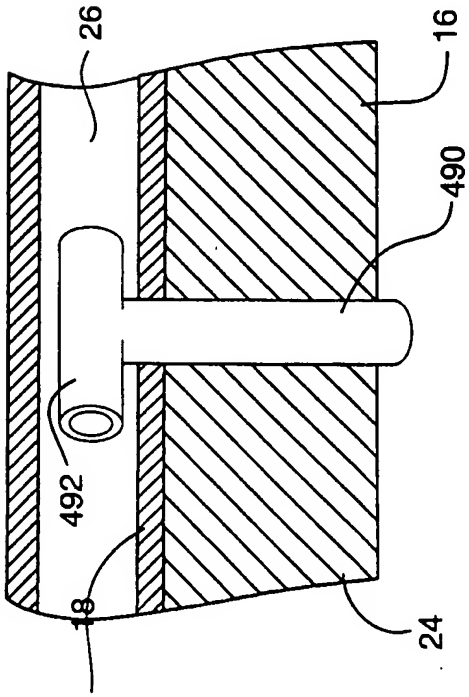

FIG. 32

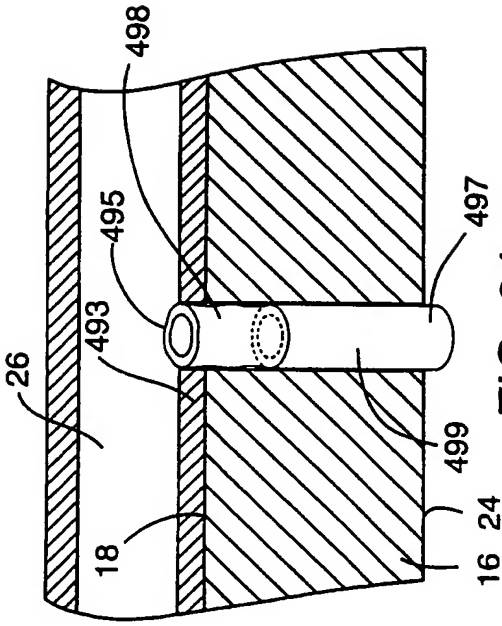

FIG. 34

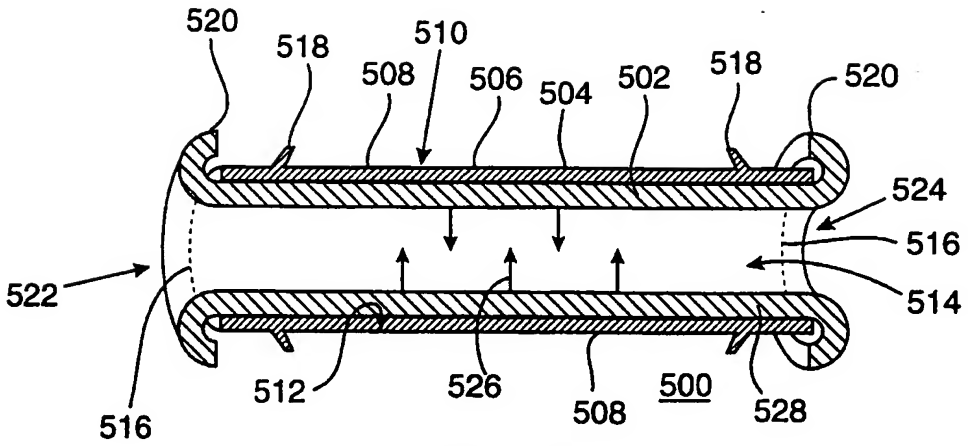
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FIG. 35

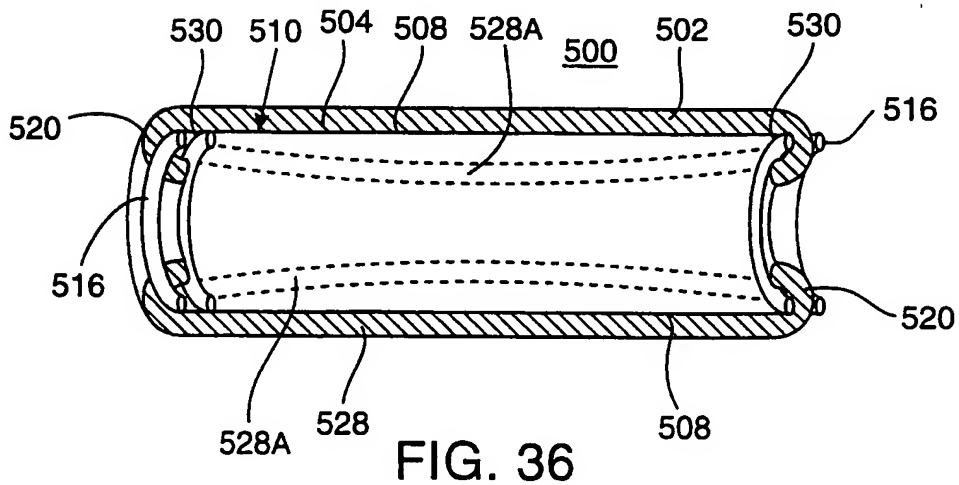
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FIG. 36

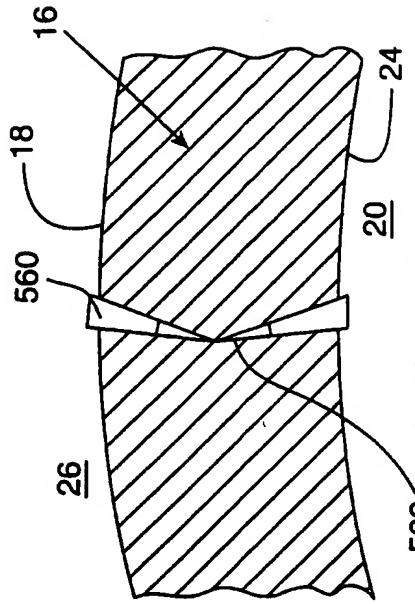


FIG. 38B

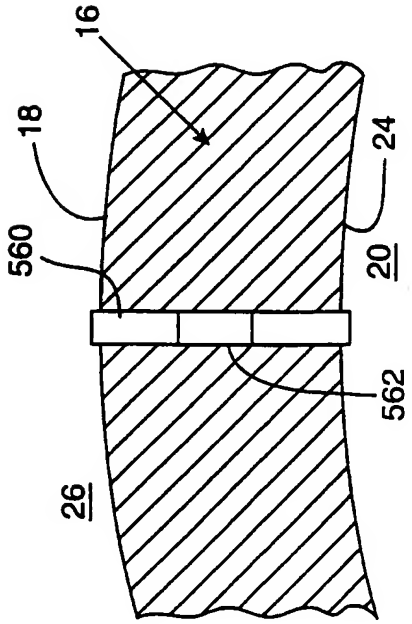


FIG. 38A

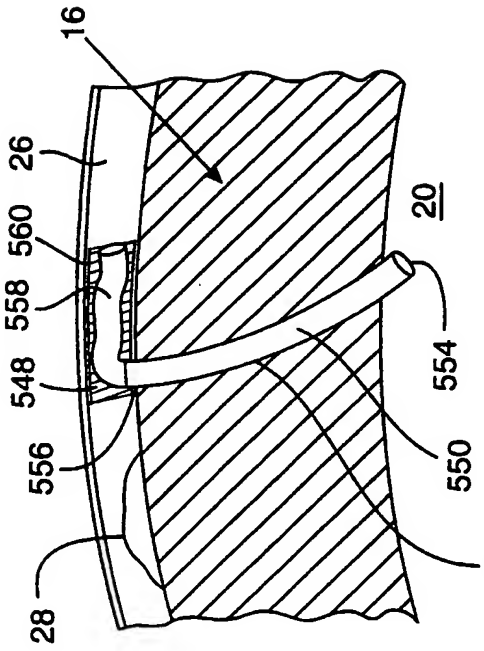
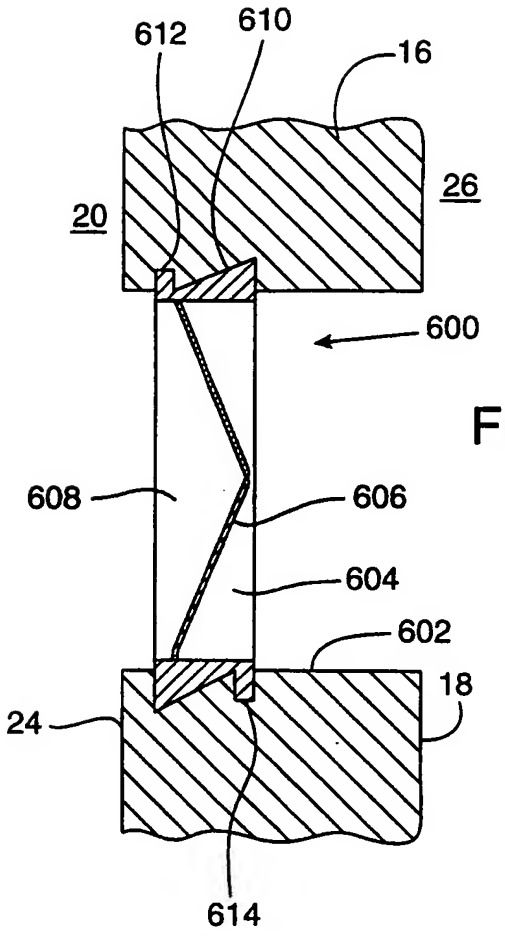


FIG. 37


612
610
16
26
20
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606
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602
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24
614

FIG. 39

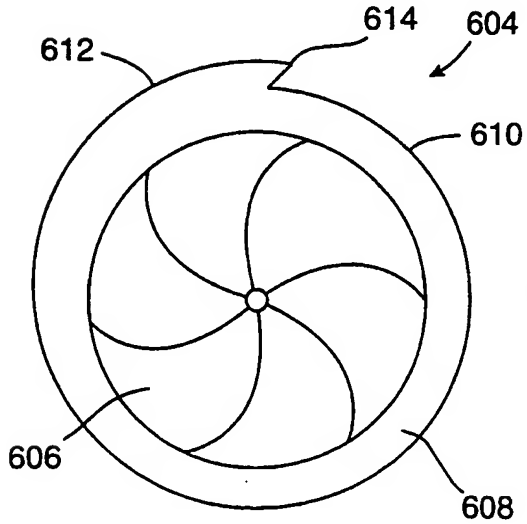
614
604
612
610
606
608

FIG. 40

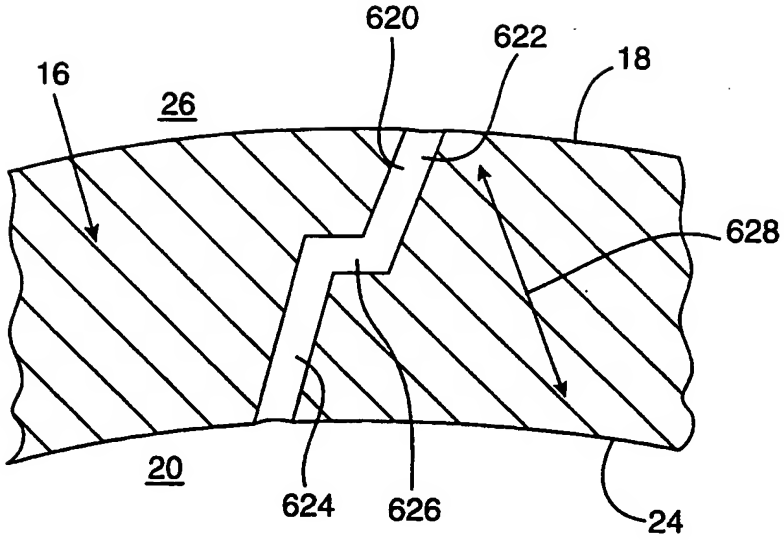

FIG. 41

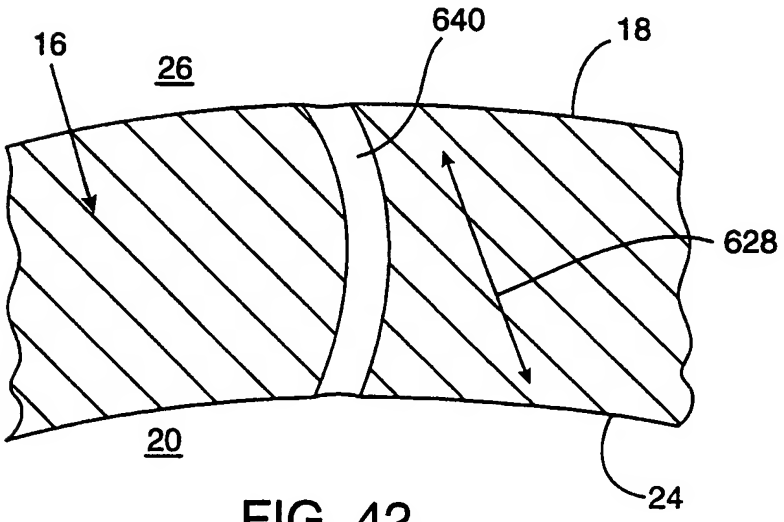

FIG. 42

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/03032

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 19/00
US CL : 128/898; 606/108, 167; 623/1, 2, 66

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/898; 606/108, 167, 1; 623/1, 2, 66, 900

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

STN, APS, WEST, DIALOG, MEDLINE, MEDLARS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US 5,843,165 A (PLAIA et al.) 01 December 1998, see entire document.	18-22
X, P	US 5,758,663 A (WILK et al.) 02 June 1998, see entire document.	1-53
X, P	US 5,855,210 A (STERMAN et al.) 05 January 1999, see entire document.	1-53
A	US 5,327,913 A (TAHERI) 12 July 1994, see entire document.	1-53

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
06 JUNE 1999	15 JUN 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer KELLY O'HARA Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet)(July 1992) *